Cancer Clinical Trials Open in Western Australia

A list of cancer clinical trials open in Western Australia that aim to improve the treatment and care of people with cancer.

Last Updated: 1 July 2017
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Disclaimer

This list of cancer clinical trials open in WA is by no means necessarily ALL clinical trials open in WA.

This list is dependent upon the information willingly provided by interested and participating hospital centres and clinicians.

On a 3 monthly basis from the inception of the website in May 2009 - the Cancer Council will undertake updates and reviews to maintain the accuracy of the listing of trials.

The Cancer Council does not accept responsibility for any loss or damage occasioned by use of the information contained on the trials listing nor from any access to it. All access and use is at the risk of the user.

Further specific information - particularly regarding an individual's personal eligibility for any potential trial should be discussed with ones treating clinician.
ANZUP 1502 Bladder Study

Registered Title
Pembrolizumab With Chemoradiotherapy as Treatment for Muscle Invasive Bladder Cancer.

Purpose
The objective of the study is to assess the safety and feasibility of combining pembrolizumab with chemoradiotherapy. The primary endpoint assessed will be safety, as defined by a satisfactorily low rate of unacceptable toxicity (G3-4 adverse events or failure of completion of planned chemotherapy and radiotherapy according to defined parameters). The secondary endpoint will be efficacy, as assessed by complete response rate of the primary tumour at first post chemoradiotherapy cystoscopic assessment. Exploratory analysis will include assessment of tumour histopathological, molecular, genetic and immunological parameters.

Lay Summary
N/A

WA Trial Sites

SCGH Medical Oncology
Ph. (08) 6383 3000

Links
US National Library of Medicine

Acknowledgements: US National Library of Medicine
JAVELIN Study

Registered Title
A Phase 3, Multicenter, Multinational, Randomized, Open-Label, Parallel-Arm Study of Avelumab* (MSB0010718C) Plus Best Supportive Care Versus Best Supportive Care Alone as a Maintenance Treatment in Patients With Locally Advanced or Metastatic Urothelial Cancer Whose Disease Did Not Progress After Completion of First-Line Platinum-Containing Chemotherapy.

Purpose
The main purpose of this study is to compare maintenance treatment with avelumab plus best supportive care (BSC) with BSC alone, to determine if avelumab has an effect on survival in patients with locally advanced or metastatic urothelial cancer that did not worsen during or following completion of first-line chemotherapy.

Lay Summary
N/A

WA Trial Sites
Tamsyn Whitcher
Murdoch Oncology Clinical Trials Unit
Ph. (08) 9428 8539
oncologytrials.murdoch@sjog.org.au

Cancer Centre Clinical Trials Unit
Caroline Stone
Clinical Trials Manager
Phone 08 615 26530 Fax 08 615 20954
caroline.stone@health.wa.gov.au

Links
US National Library of Medicine

Bone, soft tissue and other sarcomas

There are currently no bone, soft tissue and other sarcoma trials available for listing.
The ACED Trial

Registered Title  A Phase II randomised placebo-controlled, double blind, multisite study of Acetazolamide versus placebo for management of cerebral oedema in recurrent and/or progressive High Grade Glioma requiring treatment with Dexamethasone – The ACED trial.

Purpose  This study investigates whether addition of the drug acetazolamide to a dexamethasone treatment for controlling raised intracranial pressure symptoms, related to high grade glioma brain tumour (such as headache, nausea and vomiting), will allow the dexamethasone dosage to be reduced, and whether this leads to less dexamethasone-related side-effects.

Lay Summary  
Who is it for?
You can join this study if you are required to restart or increase a dexamethasone treatment to control recurrent or increased symptoms of intracranial pressure, that may be related to your brain tumour, high grade glioma.

Study details
If you like to join this study you will first be screened by your specialist to see if you meet the eligibility criteria to participate in this study. If you are deemed eligible to participate you will be randomly (by chance) assigned to one of two possible treatment groups: Group 1 will receive 1 tablet of 250mg acetazolamide twice per day for 8 weeks, in addition to the dexamethasone treatment. Group 2 will receive 1 tablet of placebo twice per day for 8 weeks, in addition to the dexamethasone treatment. Your chance to receive the group 1 treatment is equally high as to receive the group 2 treatment. You cannot choose to which group you are assigned and both you and your doctor will not know which treatment you received until the study is finished.

Participants will be asked to attend clinic visits every 2 weeks during the treatment period and then 1 more time (about 1 month after having received the last treatment). During these visits the specialist will assess your physical and mental health, and ask you about your well-being. Participants will also be asked to undergo tests and procedures, such as blood testing, scans, and questionnaire completion.

WA Trial Sites

SCGH Medical Oncology
Ph. (08) 6383 3000

Links  
Australian New Zealand Clinical Trials Registry

Acknowledgements: Australian New Zealand Clinical Trials Registry
CheckMate 548 Glioblastoma Study

**Registered Title**
A Randomized Phase 2 Single Blind Study of Temozolomide Plus Radiation Therapy Combined With Nivolumab or Placebo in Newly Diagnosed Adult Subjects With MGMT-Methylated (Tumor O6-methylguanine DNA Methyltransferase) Glioblastoma.

**Purpose**
The purpose of this study is to evaluate patients with glioblastoma that is MGMT-methylated (the MGMT gene is altered by a chemical change). Patients will receive temozolomide plus radiation therapy. They will be compared to patients receiving Nivolumab in addition to temozolomide plus radiation therapy.

**Lay Summary**
N/A

**WA Trial Sites**

[Image]

SCGH Medical Oncology  
Ph. (08) 6383 3000

**Links**
[US National Library of Medicine](#)

Acknowledgements: US National Library of Medicine
Intellance 1

Registered Title  A Randomized, Placebo Controlled Phase 2b/3 Study of ABT-414 With Concurrent Chemoradiation and Adjuvant Temozolomide in Subjects With Newly Diagnosed Glioblastoma (GBM) With Epidermal Growth Factor Receptor (EGFR) Amplification (Intellance1).

Purpose  This study seeks to determine whether the addition of ABT-414 to concomitant radiotherapy and temozolomide (TMZ) prolongs progression free survival (PFS) and overall survival (OS) in participants with newly diagnosed glioblastoma (GBM) with epidermal growth factor receptor (EGFR) amplification.

Lay Summary  N/A

WA Trial Sites  

St John of God  Ph. (08) 6464 9204

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
A Study Of Palbociclib In Combination With Letrozole As Treatment Of Post-menopausal Women With Hormone Receptor-positive, Her2-negative Advanced Breast Cancer For Whom Letrozole Therapy Is Deemed Appropriate.

A study of palbociclib in combination with letrozole as treatment of post-menopausal women with hormone receptor-positive, her2-negative advanced breast cancer for whom letrozole therapy is deemed appropriate.

N/A

Cancer Centre Clinical Trials Unit
Caroline Stone
Clinical Trials Manager
Phone 08 615 26530 Fax 08 615 20954
caroline.stone@health.wa.gov.au

US National Library of Medicine

Abbvie M12-914 Trial

Registered Title  A Phase 3 Randomized, Placebo-controlled Trial of Carboplatin and Paclitaxel With or Without the Poly ADP-ribose Polymerase (PARP) Inhibitor Veliparib (ABT-888) in Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Metastatic or Locally Advanced Unresectable Breast Cancer Gene (BRCA)-Associated Breast Cancer.

Purpose  The study seeks to evaluate the efficacy and tolerability of veliparib/placebo in combination with carboplatin and paclitaxel in HER2-negative metastatic or locally advanced, unresectable, BRCA-associated breast cancer.

Lay Summary  N/A

WA Trial Sites  Conducted at Breast Clinical Trials Unit
Ph. (08) 6500 5555

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
AREA Study

Registered Title
Randomised study to evaluate the impact of Aerobic and Resistance Exercise on fatigue in patients with advanced breast cancer (AREA study).

Purpose
The study will assess the feasibility of a specified exercise program in patients with advanced breast cancer and its impact on improving fatigue.

Lay Summary
Who is it for?
You may be eligible to join this study if you are a female with metastatic breast cancer aged between 18-80 years, and are being managed at the Mount Hospital, Perth, WA. Eligible women will also have experienced subjective fatigue in the past several weeks as a persistent symptom.

Study details
This study will be conducted in two parts. In Part 1, eligible patients will be offered a 6 week exercise program, where the primary endpoint will be to assess feasibility and overall safety. If the program is deemed as being feasible and safe, Part 2 of the study will commence. In Part 2, participants will be randomly (by chance) allocated to one of two groups. Participants in one group will be offered the 6 week exercise program, whilst participants in the other group will not participate in the exercise program.

On completion of the program, participants will be asked to complete some questionnaires to assess their levels of fatigue, depression and pain. They will also be asked to conduct a brief walking test to assess any changes in aerobic fitness.

WA Trial Sites

Conducted at Breast Clinical Trials Unit
Ph. (08) 6500 5555

Links
Australian New Zealand Clinical Trials Registry

Acknowledgements: Australia New Zealand Clinical Trials Registry
COLET Study

Registered Title  A Multistage, Phase II Study Evaluating The Safety And Efficacy Of Cobimetinib In Combination With Paclitaxel As First-Line Treatment For Patients With Metastatic Triple-Negative Breast Cancer.

Purpose  This multistage, randomized, Phase II, double-blind, multicenter, placebo-controlled trial will evaluate the safety and tolerability and estimate the efficacy of cobimetinib + paclitaxel versus placebo + paclitaxel in patients with metastatic or locally advanced, triple-negative adenocarcinoma of the breast that have not received prior systemic therapy for metastatic breast cancer (MBC). An open-label safety run-in stage of the combination cobimetinib + paclitaxel will undergo an Internal Safety Review before starting the enrollment of patients into the expansion double-blind stage of this study. Patients may continue on study treatment until the development of progressive disease, unacceptable toxicity, and/or consent withdrawal. The target sample size is 12 patients for the safety run-in stage and approximately 100 patients in the expansion stage.

Lay Summary  N/A

WA Trial Sites  

Tamsyn Whitcher  
Murdoch Oncology Clinical Trials Unit  
Ph. (08) 9428 8539  
oncologytrials.murdoch@sjog.org.au

Links  US National Library of Medicine

**Eli Lilly 13Y-MC-JPBZ (MonarcHER)**

**Registered Title**
monarcHER: A Phase 2, Randomized, Multicenter, 3-Arm, Open-Label Study to Compare the Efficacy of Abemaciclib Plus Trastuzumab With or Without Fulvestrant to Standard-of-Care Chemotherapy of Physician's Choice Plus Trastuzumab in Women With HR+, HER2+ Locally Advanced or Metastatic Breast Cancer.

**Purpose**
The purpose of this study is to evaluate the effectiveness of abemaciclib plus trastuzumab with or without fulvestrant or chemotherapy in women with hormone receptor positive (HR+), human epidermal growth factor receptor 2 positive (HER2+) locally advanced or metastatic breast cancer after prior exposure to at least two HER2-directed therapies for advanced disease.

**Lay Summary**
N/A

**WA Trial Sites**

Conducted at Breast Clinical Trials Unit
Ph. (08) 6500 5555

**Links**

Acknowledgements: US National Library of Medicine
ELIMINATE Study

Registered Title  Randomised phase II trial of neoadjuvant chemotherapy +/- concurrent aromatase inhibitor endocrine therapy to down-stage large oestrogen receptor positive breast cancer.

Purpose  This study aims to add hormone treatment (aromatase inhibitor (letrozole)) to standard neoadjuvant chemotherapy and find out if this treatment is more effective in reducing the size of large breast cancers before surgery. More effective down-staging of large breast cancers before surgery increases the likelihood of achieving a complete surgical resection and can increase the rate of breast conserving surgery.

Lay Summary  N/A

WA Trial Sites

Cancer Centre Clinical Trials Unit
Caroline Stone
Clinical Trials Manager
Phone 08 615 26530 Fax 08 615 20954
caroline.stone@health.wa.gov.au

Links  Australian New Zealand Clinical Trials Registry

Acknowledgements: Australian New Zealand Clinical Trials Registry
IMpassion (WO29522)

Registered Title  A Phase III, Multicenter, Randomized, Placebo-Controlled Study of Atezolizumab (Anti-PD-L1 Antibody) in Combination With Nab-Paclitaxel Compared With Placebo With Nab-Paclitaxel for Patients With Previously Untreated Metastatic Triple-Negative Breast Cancer.

Purpose  This multicenter, randomized, double-blind study will evaluate the efficacy, safety, and pharmacokinetics of atezolizumab (MPDL3280A) administered with nab-paclitaxel compared with placebo in combination with nab-paclitaxel in participants with locally advanced or metastatic triple-negative breast cancer (TNBC) who have not received prior systemic therapy for metastatic breast cancer (mBC). The safety of single-agent nab-paclitaxel has been determined in previous studies of participants with mBC and the safety data to date suggest that atezolizumab can be safely combined with standard chemotherapy agents.

Lay Summary  N/A

WA Trial Sites  St John of God
Ph. (08) 6464 9204

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
KATE2 (WO30085)

Registered Title  A Study to Evaluate the Efficacy and Safety of Trastuzumab Emtansine in Combination With Atezolizumab or Atezolizumab-Placebo in Participants With Human Epidermal Growth Factor-2 (HER2) Positive Locally Advanced or Metastatic Breast Cancer Who Have Received Prior Trastuzumab and Taxane Based Therapy (KATE2).

Purpose  This phase II, double-blind, randomized, placebo-controlled multicenter study will investigate the efficacy and safety of trastuzumab emtansine in combination with atezolizumab or atezolizumab-placebo in participants with HER2-positive locally advanced or metastatic breast cancer who have received prior trastuzumab and taxane based therapy, either alone or in combination, and/or who have progressed within 6 months after completing adjuvant therapy.

Lay Summary  N/A

WA Trial Sites

St John of God  Ph. (08) 6464 9204

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
Novartis CLEE011X2107 (LEE2107)

Registered Title  A Phase Ib/II, Multicenter Study of the Combination of LEE011 and BYL719 With Letrozole in Adult Patients With Advanced ER+ Breast Cancer.

Purpose  The purpose of this trial is to inform the future clinical development of the two investigational agents in ER+ breast cancer, LEE011 (CDK4/6 inhibitor) and BYL719 (PI3K-alpha inhibitor).

This is a multi-center, open-label Phase Ib/II study. The Phase Ib portion of the study is a dose escalation to estimate the MTD and/or RP2D for three regimens: two double combinations, LEE011 with letrozole and BYL719 with letrozole, followed by the triple combination of LEE011 + BYL719 with letrozole.

The Phase Ib will be followed by a randomized Phase II study to assess the preliminary anti-tumor activity of the two double combination regimens (LEE011+letrozole and BYL719+letrozole) versus the triple combination (LEE011+BYL719 with letrozole) and to further evaluate their safety in patients with ER+/HER2- locally advanced or metastatic breast cancer.

Approximately 300 adult women with ER+/HER2- locally advanced or metastatic breast cancer will be enrolled.

Lay Summary  N/A

WA Trial Sites  

Conducted at Breast Clinical Trials Unit
Ph. (08) 6500 5555

Links  

US National Library of Medicine

Acknowledgements: US National Library of Medicine
Registered Title: A Randomized Phase II Study of MCS110 Combined With Carboplatin and Gemcitabine in Advanced Triple Negative Breast Cancer (TNBC).

Purpose: To determine whether MCS110 antibody therapy improves the efficacy of carboplatin and gemcitabine (carbo/gem) in advanced TNBC patients.

Lay Summary: N/A

WA Trial Sites: Conducted at Breast Clinical Trials Unit
Ph. (08) 6500 5555

Links: US National Library of Medicine

Acknowledgements: US National Library of Medicine
OLYMPIA Study

Registered Title  A Randomised, Double-blind, Parallel Group, Placebo-controlled Multi-centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients With germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy.

Purpose  Olaparib treatment in patients with germline BRCA1/2 mutations and high risk HER2 negative primary breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy.

Lay Summary  N/A

WA Trial Sites

SCGH Medical Oncology
Ph. (08) 6383 3000

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
PALLAS (ANZ 1603, AFT-05, ABCSG 42, BIG 14-03)

Registered Title  PALbociclib CoLlaborative Adjuvant Study: A Randomized Phase III Trial of Palbociclib With Standard Adjuvant Endocrine Therapy Versus Standard Adjuvant Endocrine Therapy Alone for Hormone Receptor Positive (HR+) / Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Early Breast Cancer.

Purpose  This is a prospective, two arm, international, multicenter, randomized, open-label Phase III study evaluating the addition of 2 years of palbociclib to standard adjuvant endocrine therapy for patients with HR+ / HER2- early breast cancer (EBC). The purpose of the PALLAS study is to determine whether the addition of palbociclib to adjuvant endocrine therapy will improve outcomes over endocrine therapy alone for HR+/HER2- early breast cancer. Assessment of a variety of correlative analysis, including evaluation of the effect of palbociclib in genomically defined tumor subgroups, is planned.

Lay Summary  N/A

WA Trial Sites

Conducted at Breast Clinical Trials Unit
Ph. (08) 6500 5555

Cancer Centre Clinical Trials Unit
Caroline Stone
Clinical Trials Manager
Phone 08 615 26530 Fax 08 615 20954
caroline.stone@health.wa.gov.au

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
PENELOPE-B

Registered Title
Phase III study evaluating palbociclib (PD-0332991), a Cyclin-Dependent Kinase (CDK) 4/6 Inhibitor in patients with hormone-receptor-positive, HER2-normal primary breast cancer with high relapse risk after neoadjuvant chemotherapy.

Purpose
The PENELOPEB study is designed to demonstrate that in the background of standard anti-hormonal therapy palbociclib provides superior invasive disease-free survival (iDFS) compared to placebo in pre- and postmenopausal women with HR-positive/HER2-normal early breast cancer at high risk of relapse after showing less than pathological complete response to neoadjuvant taxane-containing chemotherapy. Considering the high risk of recurrence in patients after neoadjuvant chemotherapy and a high CPS-EG score, palbociclib appears to be an attractive option with a favourable safety profile for these patients.

Lay Summary
N/A

WA Trial Sites
Cancer Centre Clinical Trials Unit
Caroline Stone
Clinical Trials Manager
Phone 08 615 26530 Fax 08 615 20954
caroline.stone@health.wa.gov.au

Links
US National Library of Medicine

Acknowledgements: US National Library of Medicine

The best available evidence suggests that pregnancy after breast cancer does not increase a woman's risk of developing a recurrence from her breast cancer. In particular, the most recent data suggest that this is the case also in women with a hormone receptor-positive breast cancer. There is also no indication of increased risk for delivery complications or for the newborn. The aim of the study is to investigate if temporary interruption of endocrine therapy, with the goal to permit pregnancy, is associated with a higher risk of breast cancer recurrence. The study aims also to evaluate different specific indicators related to fertility, pregnancy and breast cancer biology in young women. A psycho-oncological companion study on fertility concerns, psychological well-being and decisional conflicts will be conducted in interested Centers.

N/A

St John of God
Ph. (08) 6464 9204

US National Library of Medicine

Acknowledgements: US National Library of Medicine
POSNOC Study

Registered Title  POSNOC - POsitive Sentinel NOde: Adjuvant Therapy Alone Versus Adjuvant Therapy Plus Clearance or Axillary Radiotherapy. A Randomised Controlled Trial of Axillary Treatment in Women With Early Stage Breast Cancer Who Have Metastases in One or Two Sentinel Nodes.

Purpose  POSNOC is a pragmatic, randomised, multicentre, non-inferiority trial. For women with early stage breast cancer and one or two sentinel node macrometastases, to assess whether adjuvant therapy alone is no worse than adjuvant therapy plus axillary treatment, in terms of axillary recurrence within 5 years.

Lay Summary  N/A

WA Trial Sites  St John of God
Ph. (08) 6464 9204

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
PUMA-NER-6201

Registered Title  An Open-Label Study to Characterize the Incidence and Severity of Diarrhea in Patients With Early-Stage HER2+ Breast Cancer Treated With Neratinib and Intensive Loperamide Prophylaxis.

Purpose  The primary objective of this study is to characterize the incidence and severity of diarrhea in patients with early-stage HER2 overexpressed/amplified (HER2+) breast cancer treated with neratinib when administered with intensive loperamide prophylaxis, after prior treatment with trastuzumab.

Lay Summary  N/A

WA Trial Sites

Conducted at Breast Clinical Trials Unit
Ph. (08) 6500 5555

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
ROLLIS Randomised Controlled Trial

Registered Title
Can Radio-guided Occult Lesion Localisation using Iodine-125 Seeds (ROLLIS) for excision of impalpable breast cancer reduce the rate of pathologically inadequate margins and/or subsequent oncological surgery compared with standard hook-wire localisation? A randomised controlled clinical trial.

Purpose
This study is comparing the use of low dose radioactive seeds to standard treatment for surgical removal guidance in breast cancer patients.

Lay Summary
Who is it for?
You may be eligible to join this study, if you are a female aged 18 years or above and have been diagnosed with breast cancer that is non-palpable (i.e. the surgeon cannot feel it), and thus require a procedure known as localisation.

Trial details
When an abnormal area in the breast needs to be removed after a needle biopsy (and the surgeon cannot feel it), the abnormal area is localised. We are comparing two different localisation techniques in this study. Participants will be randomly (by chance) assigned to one of two techniques. Participants in one group will undergo a procedure known as ROLLILS (radio-guided occult lesion localisation and removal of impalpable breast cancers). This involves inserting a low-dose sterilised radioactive iodine seed into the patient's cancer under local anaesthesia with imaging guiding.

The patient will then undergo breast conserving surgery within 4 days, during which the surgeon uses the seed to guide removal of the impalpable cancer. Participants in the other group will undergo the standard treatment, known as hook-wire guided localisation (HWL). This is when a hook-wire is placed in the breast on the day of breast conserving surgery by a radiologist. Participants are followed for up to 5 years post-surgery in order to evaluate clinical and cosmetic outcomes, disease recurrence and patient satisfaction. A cost benefit analysis will also be undertaken.

WA Trial Sites
This trial is open at Sir Charles Gairdner Hospital and Royal Perth Hospital.
Dr Shashi Aggarwal
ROLLIS Research Coordinator
Ph: +61 8 9224 3649 (RPH)
Ph: +61 8 9346 1834 (SCGH)
shashi.aggarwal@health.wa.gov.au

Links
Australian New Zealand Clinical Trials Registry

Acknowledgements: Australia New Zealand Clinical Trials Registry
**SANDPIPER Study**

**Registered Title**  
A Phase III, Double-Blind, Placebo Controlled, Randomized Study Of Taselisib Plus Fulvestrant Versus Placebo Plus Fulvestrant In Postmenopausal Women With Estrogen Receptor-Positive And Her2-Negative Locally Advanced Or Metastatic Breast Cancer Who Have Disease Recurrence Or Progression During Or After Aromatase Inhibitor Therapy.

**Purpose**  
This international, multicenter, randomized, double-blinded, placebo-controlled study is designed to compare the efficacy and safety of taselisib + fulvestrant with that of placebo + fulvestrant in postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor-2 (HER2)-negative, PIK3CA-mutant, unresectable, locally advanced or metastatic breast cancer after recurrence or progression during or after an aromatase inhibitor (AI) therapy. There will be a 2:1 randomization to the taselisib arm versus the placebo arm. Enrollment will be enriched for patients with PIK3CA mutant tumors via central testing. The anticipated duration of the study is approximately 3.5 years.

**Lay Summary**  
N/A

**WA Trial Sites**

![St John of God Murdoch Hospital](image)

Tamsyn Whitcher  
Murdoch Oncology Clinical Trials Unit  
Ph. (08) 9428 8539  
oncologytrials.murdoch@sjog.org.au

**Links**  

Colorectal

Advanced metastatic colorectal cancer

Registered Title
An open-label early access phase IIIb study of trifluridine / tipiracil (S 95005/TAS-102) in patients with a pretreated metastatic colorectal cancer.

Purpose
An early access study of trifluridine / tipiracil (S 95005/TAS-102) in patients with a pretreated metastatic colorectal cancer.

Lay Summary
The research project is testing trifluridine/tipiracil (also known as S95005 or TAS-102) in patients with metastatic colorectal cancer. It is offered as a third line (or later) treatment. The drug is given orally (10 days of treatment every 28 days) and is approved in Japan, United States and in the European Union under the trade name of Lonsurf®. It has not been approved treatment for metastatic colorectal cancer in Australia and is therefore an experimental treatment.

WA Trial Sites

Mount Hospital Clinical Trials
Ph. (08) 9481 8373

Links
EU Clinical Trials Register

Acknowledgements: EU Clinical Trials Register
ALT GIST Study

Registered Title  A Randomised Phase II Trial of Imatinib Alternating With Regorafenib Compared to Imatinib Alone for the First Line Treatment of Advanced Gastrointestinal Stromal Tumour (GIST).

Purpose  An open label randomised trial for adults with histologically confirmed measurable metastatic GIST who have received no other treatment for metastatic disease. The study aims to determine if an alternating regimen of imatinib and regorafenib has sufficient activity and safety in comparison to imatinib alone to warrant further evaluation as a first line treatment for metastatic GIST.

Lay Summary  N/A

WA Trial Sites

SCGH Medical Oncology
Ph. (08) 6383 3000

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
ASCOLT Study

Registered Title
Aspirin for Dukes C and High Risk Dukes B Colorectal Cancers - An International, Multi-Center, Double Blind, Randomized Placebo Controlled Phase III Trial.

Purpose
We hypothesize through this randomized, placebo-controlled adjuvant study, that Aspirin in patients with dukes C or high risk dukes B colorectal cancer (ASCOLT) can improve survival in this patient population over placebo control. If indeed found to be beneficial, because aspirin is cheap and easy to administer, it will positively impact the lives of many individuals in Asia and globally.

Lay Summary
N/A

WA Trial Sites
SCGH Medical Oncology
Ph. (08) 6383 3000

St John of God
Ph. (08) 6464 9204

Links
US National Library of Medicine

Acknowledgements: US National Library of Medicine
CHALLENGE Study

Registered Title A Phase III Study of the Impact of a Physical Activity Program on Disease-Free Survival in Patients With High Risk Stage II or Stage III Colon Cancer: A Randomized Controlled Trial (CHALLENGE).

Purpose This randomized phase III trial is studying a physical activity program given together with health education materials to see how well it works compared with giving health education materials alone for patients who have undergone treatment for high-risk stage II or stage III colon cancer.

Lay Summary Participating in a physical activity program designed to increase free time physical activity and receiving written health education materials may influence the chance of cancer recurring as well as impact on physical fitness, psychological well-being and the quality of life of patients who have undergone surgery and chemotherapy for colon cancer. It is not yet known whether giving a physical activity program together with health education materials is more effective than giving health education materials alone for patients who have undergone colon cancer treatment.

WA Trial Sites

Cancer Centre Clinical Trials Unit
Caroline Stone
Clinical Trials Manager
Phone 08 615 26530 Fax 08 615 20954
caroline.stone@health.wa.gov.au

Links US National Library of Medicine

Acknowledgements: US National Library of Medicine
DYNAMIC Study

Registered Title  A study to evaluate the use of circulating tumour DNA to guide adjuvant chemotherapy on recurrence-free survival in patients with stage II Colon or rectal cancer.

Purpose  This study will determine the effect of the use of circulating tumour DNA (ctDNA) to guide adjuvant chemotherapy on recurrence-free survival in stage II colon or rectal cancer patients.

Lay Summary  Who is it for?

You may be eligible to join this study if you are aged 18 years or above, and have been diagnosed with Stage II colon or rectal cancer and have had your cancer curatively resected.

Study details

Participants in this study are randomly allocated (by chance) to one of two groups. Participants in one group will have blood samples taken and analysed for circulating tumour DNA (ctDNA) and be treated according to the ctDNA results. Those with positive ctDNA results will receive standard 5FU-based adjuvant chemotherapy (either single agent or combined with oxaliplatin), while those with negative ctDNA will not receive adjuvant chemotherapy. Participants in the other group will have a blood sample taken, but the ctDNA result will not be disclosed. Patients in this group will be treated according to standard clinical criteria at the discretion of the treating physician. Participants who had positive ctDNA results and are being treated with adjuvant chemotherapy will have monthly blood samples taken during treatment to track ctDNA levels. All participants will be followed up 3 monthly for 2 years, then 6 monthly for 3 years through their hospital for a total of five years for disease recurrence and survival.

WA Trial Sites

Cancer Centre Clinical Trials Unit
Caroline Stone
Clinical Trials Manager
Phone 08 615 26530 Fax 08 615 20954
caroline.stone@health.wa.gov.au

Links  Australian New Zealand Clinical Trials Registry

Acknowledgements: Australian New Zealand Clinical Trials Registry
KEYNOTE-177

Registered Title  A Phase III Study of Pembrolizumab (MK-3475) vs. Chemotherapy in Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Stage IV Colorectal Carcinoma (KEYNOTE-177).

Purpose  In this study, participants with MSI-H or dMMR advanced colorectal carcinoma will be randomly assigned to receive either pembrolizumab or the Investigator’s choice of 1 of 6 standard of care (SOC) chemotherapy regimens for the treatment of advanced colorectal carcinoma. The primary study hypothesis is that pembrolizumab will prolong progression-free survival (PFS) compared to current SOC chemotherapy.

Lay Summary  N/A

WA Trial Sites

St John of God
Ph. (08) 6464 9204

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
# Gynaecological

## CAELYX YONDELIS Study

**Registered Title**  
A Randomized, Open-Label Study Comparing the Combination of YONDELIS and CAELYX With CAELYX Monotherapy for the Treatment of Advanced-Relapsed Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancer.

**Purpose**  
The purpose of this study is to assess the efficacy and safety of trabectedin+DOXIL as a third-line chemotherapy regimen (treatment) in patients with platinum-sensitive advanced-relapsed epithelial ovarian, primary peritoneal, or fallopian tube cancer who received 2 previous lines of platinum-based chemotherapy.

**Lay Summary**  
N/A

**WA Trial Sites**

![St John of God](image)

St John of God  
Ph. (08) 6464 9204

**Links**  
[US National Library of Medicine](http://us.nationallibraryofmedicine)

Acknowledgements: US National Library of Medicine
feMMe Endometrial Cancer Study

Registered Title
A Phase II Randomised Clinical Trial of Mirena® ± Metformin ± Weight Loss Intervention in Patients With Early Stage Cancer of the Endometrium.

Purpose
Currently the standard treatment for early stage endometrial cancer or endometrial hyperplasia with atypia is a total hysterectomy (an operation to remove the uterus) and removal of both ovaries. While highly effective, this surgery carries significant side effects for:

- young women who still wish to have children and would lose fertility; and
- women with one or more disorders (or diseases) in addition to the early stage endometrial cancer or endometrial hyperplasia with atypia and/or morbid obesity who are at risk for surgical complications making surgery unsafe.

This study will assess a new approach to the treatment of endometrial cancer to spare women of having to undergo major surgery that may be unwanted or unnecessary.

Mirena is approved in Australia for contraception, to treat heavy bleeding, and to prevent thickening of the lining of the uterus (endometrial hyperplasia) during oestrogen replacement therapy (HRT). However it is not approved to treat early stage endometrial cancer or endometrial hyperplasia with atypia. This research project will test to see if Mirena is an effective treatment for early stage endometrial cancer and endometrial hyperplasia with atypia.

Metformin is approved in Australia to treat Diabetes. However it is not approved to treat early stage endometrial cancer or endometrial hyperplasia with atypia. Therefore, it is an experimental treatment for early stage endometrial cancer and endometrial hyperplasia with atypia. This means that it must be tested to see if it is an effective treatment for early stage endometrial cancer and endometrial hyperplasia with atypia.

Weight loss interventions are feasible and safe, and already being implemented by gynaecologic oncologist to make women eligible for surgery. Weight loss of 7% body weight induces a large biological effect (for example reduces incidence of diabetes by 58%, and hypertension by 26%).

Lay Summary
N/A

WA Trial Sites
St John of God
Ph. (08) 6464 9204

Links
US National Library of Medicine

Acknowledgements: US National Library of Medicine
FROCS

Registered Title  Mindfulness Based Cognitive Therapy for Fear of Recurrence in Ovarian Cancer Survivors. (FROCS)

Purpose  This study will determine the effect of mindfulness based cognitive therapy on the fear of recurrence in ovarian cancer survivors.

Lay Summary  Who is it for?

You may be eligible to join this study if you are aged 18 years or above and have been diagnosed with ovarian cancer, have completed all hospital based adjuvant treatment and are now disease free.

Study details

All participants will receive the same intervention and will involve intensive training and practice in mindfulness based cognitive therapy. Treatment is designed as an 8 week course of 2-2.5 hour small group sessions once weekly with approximately 8-15 individuals in each group. Sessions are run at locations in Shenton Park, Duncraig and East Fremantle by the Cancer Council WA, or by SolarisCare Foundation, at Sir Charles Gardner Hospital in Nedlands. Courses take place during the day and are free of charge. The groups will be run by experienced clinicians in psychotherapy, counselling and meditation and will have a clinician manual and a participant workbook outlining the themes and exercises for each week. Group members will be expected to practice skills between sessions. Participants will be asked to answer questionnaires before, during and after the group sessions to collect information on how participants are feeling.

WA Trial Sites

St John of God
Ph. (08) 6464 9204

Links  Australian New Zealand Clinical Trials Registry

Acknowledgements: Australian and New Zealand Clinical Trials Registry
**LACC Cervical Cancer Study**

<table>
<thead>
<tr>
<th><strong>Registered Title</strong></th>
<th>A Phase III Randomized Clinical Trial of Laparoscopic or Robotic Radical Hysterectomy Versus Abdominal Radical Hysterectomy in Patients With Early Stage Cervical Cancer.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>The goal of this clinical research study is to compare the long-term outcomes of different surgical methods for the treatment of cervical cancer. The long-term outcome of a total abdominal radical hysterectomy (TARH) will be compared against laparoscopy. In this study, the laparoscopy will be done with or without robotic technology.</td>
</tr>
<tr>
<td><strong>Lay Summary</strong></td>
<td>N/A</td>
</tr>
</tbody>
</table>
| **WA Trial Sites**   | **St John of God**  
Ph. (08) 6464 9204  
[St John of God logo](#) |
| **Links**            | [US National Library of Medicine](#)  
Acknowledgements: US National Library of Medicine |
Outback Study

Registered Title A Phase III trial of adjuvant chemotherapy following chemoradiation as primary treatment for locally advanced cervical cancer compared to chemoradiation alone.

Purpose This randomized phase III trial studies how well giving cisplatin and radiation therapy together with or without carboplatin and paclitaxel works in treating patients with locally advanced cervical cancer.

Lay Summary Drugs used in chemotherapy, such as cisplatin, carboplatin, and paclitaxel, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. External radiation therapy uses high-energy x rays to kill tumor cells. Internal radiation uses radioactive material placed directly into or near a tumor to kill tumor cells. It is not yet know whether giving cisplatin and external and internal radiation therapy together with carboplatin and paclitaxel kill more tumor cells.

Who is it for? You can join this study if you have locally advanced cervical cancer which is suitable for primary treatment with chemoradiation and you have not received any previous pelvic radiotherapy.

Trial details Participants will be divided into two groups. Both groups will be treated with standard external beam radiation treatment to the pelvis and brachytherapy (internal radiotherapy). They will receive cisplatin intravenously during the radiation at a dose of 40mg/m2 weekly for 5 doses. One group will also receive 4 cycles of 3 weekly adjuvant chemotherapy using carboplatin and paclitaxel intravenously, beginning within 4 weeks of completion of all radiation treatment.

The study aims to see whether the adjuvant chemotherapy increases the response to treatment and improves survival times.

WA Trial Sites

SCGH Medical Oncology Ph. (08) 6383 3000

Links US National Library of Medicine Australian New Zealand Clinical Trials Registry

Acknowledgements: US National Library of Medicine, Australian New Zealand Clinical Trials Registry
Sexual Healing

Registered Title
A Randomised, Controlled Trial on the Effect of Pre-Operative Sexual Counselling on Sexuality and Quality of Life after Risk-Reducing Salpingo-oophrectomy.

Purpose
This study will determine the effect of pre-operative sexual counselling on sexuality and quality of life after risk reducing salpingo-oophorectomy (RRSO) in women at high risk of ovarian cancer.

Lay Summary
Who is it for?
You may be eligible to join this study if you are aged 18 years or above, at high risk of ovarian cancer and have decided to undergo risk-reducing salpingo-oophorectomy.

Study details
Participants in this study are randomly allocated (by chance) to one of two groups. Participants in one group will receive a single pre-operative counselling session with a sexologist to discuss the potential effects of surgery on sexual function and physical changes, potential changes to intimacy, loss of sexual self-esteem related to body image changes, menopausal symptoms and confidence, changes to sexual response such as reduced arousal, loss of libido, difficulty reaching orgasm, menopausal symptoms related to treatment including hot flushes/night sweats, disturbed sleep, poor memory and weight gain, all of which may impact on one's sexual self esteem, sexual functioning and general wellbeing (quality of life).

While participants in the other group will receive routine care which is the initial consultation with your gynaecologic oncology specialist who may or may not discuss such issues with you. Participants will be followed-up for up to 12 months post-surgery to determine the effect on sexual function, the prevalence and severity of sexual difficulties after RRSO, and any other factors that significantly affect sexual function and quality of life. Serum testosterone levels will also be tested to determine whether there is a correlation with sexual function after RRSO.

WA Trial Sites

St John of God
Ph. (08) 6464 9204

Links
Australian New Zealand Clinical Trials Registry

Acknowledgements: Australian and New Zealand Clinical Trials Registry
Velia Study

Registered Title A Phase 3 Placebo-Controlled Study of Carboplatin/Paclitaxel With or Without Concurrent and Continuation Maintenance Veliparib (PARP Inhibitor) in Subjects With Previously Untreated Stages III or IV High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.

Purpose The focus of this study is to evaluate the efficacy, safety, and tolerability of veliparib in women with previously untreated, Stage III or IV, high-grade serous, epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Lay Summary N/A

WA Trial Sites

St John of God
Ph. (08) 6464 9204

Links US National Library of Medicine

Acknowledgements: US National Library of Medicine
Vulval Study

Registered Title
Prospective collection of clinical data following sentinel node biopsy for vulval carcinoma in Australia and New Zealand.

Purpose
This study aims to prospectively collect clinical data following sentinel node biopsy for vulval carcinoma in Australia and New Zealand. You may be eligible to join this study if you are a female aged 18 years or above with histologically confirmed, unifocal invasive squamous cell carcinoma of vulva less than 4cm in greatest dimension.

Lay Summary
Women in Australia and New Zealand women with early vulval cancer will be offered sentinel node procedures in place of groin node dissection.

On the day before or the morning of your operation, you will have a small injection of a radioactive marker into the skin next to the cancer. A local anaesthetic cream will be used to reduce any discomfort from this injection. Pictures will then be taken over the next 2 1/2 hours to see which glands the marker has spread to. The marker will also help us find the ‘sentinel nodes’ during your operation. Either on the afternoon after the injection or the next day you will have your operation as planned by your doctor. Whilst you are asleep we will inject some blue dye around the cancer which will also help us to identify the sentinel glands. During the 60 minute operation we will remove the cancer. We will identify and remove the sentinel lymph gland(s) from one or both groins. When sentinel nodes in one or two groins can not be identified a full removal of the groin nodes (lymphadenectomy) on either one or both sides will be performed. The gland(s) will be sent to the laboratory for detailed assessment by the pathologist. Follow up clinical data will be collected from your clinical records at 3, 12, 24 and 36 months after surgery, from information obtained when you attend outpatients clinic. The majority of women with early vulval carcinoma do not have groin node metastasis and these women are unlikely to benefit from groin node dissection. The use of sentinel node dissection is safe and should be part of the standard treatment for women with early stage vulvar cancer.

WA Trial Sites

St John of God
Ph. (08) 6464 9204

Links
Australian New Zealand Clinical Trials Registry

Acknowledgements: Australian and New Zealand Clinical Trials Registry
Acute Myeloid Leukaemia

AG-21-AML-005

Registered Title  A Phase 1b/2 Open-Label, Randomized Study of 2 Combinations of Isocitrate Dehydrogenase (Idh) Mutant Targeted Therapies Plus Azacitidine: Oral Ag-120 Plus Subcutaneous Azacitidine and Oral Ag-221 Plus Sc Azacitidine in Subjects with Newly Diagnosed Acute Myeloid Leukemia Harboring an Idh1 or an Idh2 Mutation, Respectively, Who are Not Candidates to Receive Intensive Induction Chemotherapy.

Purpose  This Phase 1b/2 study is an open-label, randomized, multicentre trial to evaluate the safety and efficacy of oral AG-120 + SC azacitidine and oral AG-221 + SC azacitidine in subjects with newly diagnosed AML harbouring an IDH1 or an IDH2 mutation, respectively. The study population consists of subjects who are not candidates to receive intensive Inductive Chemotherapy (IC).

The study comprises a Phase 1b dose-escalation stage and a Phase 2 randomized stage. The Phase 1b stage is an open-label dose-finding study to evaluate the safety and tolerability of the combinations of oral AG-120 and oral AG-221 with SC azacitidine to define the RP2Ds of these 2 agents when administered in combination with SC azacitidine.

The Phase 2 stage is an open-label randomized study to evaluate the efficacy of the combinations of oral AG-120 and oral AG-221 with SC azacitidine versus SC azacitidine alone in order to assess the overall response rate (ORR), event-free survival (EFS), and morphologic complete remission (CR).

The Primary Objective for both phases of the study is to assess the efficacy of the combination treatments of oral AG-120 plus SC azacitidine and oral AG-221 + SC azacitidine versus SC azacitidine in subjects with newly diagnosed AML harbouring an IDH1 or an IDH2 mutation, respectively, who are not candidates to receive intensive IC.

Lay Summary  N/A

WA Trial Sites

Royal Perth Hospital

RPH Haematology
Ph. (08) 9224 2405

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
AML M16

Registered Title  Sorafenib in combination with intensive chemotherapy for previously untreated adult FLT3-ITD positive AML: a phase 2 randomised double-blind placebo controlled multi-centre study.

Purpose  The purpose of this study is to compare the effects, good and/or bad, of a standard chemotherapy regimen for FLT3 positive AML, combined with or without Sorafenib, to find out which is better.

Lay Summary  This study will look at patients with a specific type of Acute Myeloid Leukaemia (AML) called FLT3 positive AML.

This research is being done because we do not know whether the addition of Sorafenib to chemotherapy treatment is better than chemotherapy treatment alone for FLT3 positive AML. Sorafenib has been tested in over 8,400 patients and is being studied in a number of illnesses, including Acute Myeloid Leukaemia (AML) and in Kidney, Skin, Lung and Liver Cancer. Sorafenib blocks a cell surface receptor called FLT3, which has an important role in the survival and growth of AML cells. Not all leukaemia cells will have the abnormal FLT3 gene. This study will focus only on patients with leukaemia cells detected to have an abnormal FLT3 gene ('FLT3-positive AML').

Sorafenib is an investigational drug, which means it has not been approved for use in AML by government health authorities, such as the Australian Therapeutic Goods Administration (TGA) or any other agency, but is permitted to be tested in research studies such as this one. Sorafenib is only approved for use in Australia for certain types of Liver Cancer and Kidney Cancer.

WA Trial Sites

Haematology Care Centre
Sir Charles Gairdner Hospital
Ph. (08) 6383 3207
Fax (08) 9346 4432
Email: louise.hay@health.wa.gov.au

Links  Australian New Zealand Clinical Trials Registry
**CASCADE Study**

**Registered Title**
A randomized, double-blind phase 3 study of vadastuximab talirine (SGN-CD33A) versus placebo in combination with azacitidine or decitabine in the treatment of older patients with newly diagnosed acute myeloid leukemia (AML).

**Purpose**
The primary aims of this study is to compare the overall survival of participants who receive vadastuximab talirine (SGN-CD33A) versus placebo in combination with a Hypomethylating agent (either azacitidine or decitabine) in the treatment of older patients with newly diagnosed Acute Myeloid Leukaemia.

The study also aims to evaluate safety profiles and overall survival in the two treatment arms as well as to compare the; composite complete remission rates between the two treatment arms - event-free survival rates between the two treatment arms - leukaemia free survival rates between the two treatment arms - time to response rates between the two treatment arms.

**Lay Summary**
N/A

**WA Trial Sites**

![Royal Perth Hospital](Link to image)

RPH Haematology
Ph. (08) 9224 2405

**Links**
[US National Library of Medicine](Link to website)

Acknowledgements: US National Library of Medicine
**Dacitabine Study**

**Registered Title**  
A Randomized Phase 2 Study of DACOGEN (Decitabine) Plus JNJ-56022473 (Anti-CD123) Versus DACOGEN (Decitabine) Alone in Patients With AML Who Are Not Candidates for Intensive Chemotherapy.

**Purpose**  
This is a 2-part, open-label, multicentre, Phase 2 study conducted in participants with AML who are suitable for experimental therapy (Part A) and in participants with untreated AML who are not eligible for intense induction chemotherapy or hematopoietic stem cell transplantation (HSCT) (Part B).

The primary objective of study Part A is to assess the safety of talacotuzumab (formerly CSL362) monotherapy and confirm the recommended Phase 2 dose (RP2D) in participants with acute myeloid leukemia (AML) for whom experimental therapy is appropriate.

The primary objective of study Part B are to assess complete response (CR) rate and overall survival (OS) in participants with AML who are not eligible for intense induction chemotherapy and who are randomly assigned to receive decitabine plus talacotuzumab at the RP2D or decitabine alone.

**Lay Summary**  
N/A

**WA Trial Sites**  
![Royal Perth Hospital](image)

RPH Haematology  
Ph. (08) 9224 2405

**Links**  

Acknowledgements: US National Library of Medicine
**IMG-7289-CTP-101 AML Study**

**Registered Title**
A Multi-Center, Open Label Study to Assess the Safety, Steady-State Pharmacokinetics and Pharmacodynamics of IMG-7289 with and without ATRA (Tretinoin) in Patients with Advanced Myeloid Malignancies.

**Purpose**
This is a Phase 1 open label study of the dose and duration of an orally administered LSD1 inhibitor, IMG-7289, in patients with acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). Some participants may also receive all-trans retinoic acid (ATRA; also known as tretinoin and Vesanoid®) in combination with IMG-7289.

**Lay Summary**
N/A

**WA Trial Sites**

![Fiona Stanley Hospital Haematology](image)

Fiona Stanley Hospital Haematology
Ph. (08) 08 6152 6540

**Links**
US National Library of Medicine

Acknowledgements: US National Library of Medicine
QuANTUM-First Study

Registered Title
A Phase 3, Double-Blind, Placebo-controlled Study of Quizartinib (AC220) Administered in Combination with Induction and Consolidation Chemotherapy, and Administered as Maintenance Therapy in Subjects 18 to 75 Years Old with Newly Diagnosed FLT3-ITD (+) Acute Myeloid Leukemia.

Purpose
The research project is testing a new treatment for acute myeloid leukaemia (AML). The new treatment is called Quizartinib. The purpose of this research study is to test how well the study medication, Quizartinib, works when taken with standard chemotherapy to put AML into remission and then taken alone to prevent relapses of AML. The type of AML being studied in this clinical trial is known as FLT3-ITD positive AML. This type of AML has an alteration (or mutation) in genes, which may indicate a worse prognosis. Quizartinib works by changing the activity of the FLT3-ITD mutation. Some participants in other studies using Quizartinib had either a complete or a partial remission of their AML, whereas some patients had no response.

Lay Summary
N/A

WA Trial Sites

Fiona Stanley Hospital Haematology
Ph. (08) 08 6152 6540

Links
US National Library of Medicine

Acknowledgements: US National Library of Medicine
WA ALLG National Blood Cancer Registry

Registered Title
Australasian Leukaemia and Lymphoma Group Common Acute Myeloid Leukaemia Registry.

Purpose
The purpose of this registry is to collect information on selected patients with a suspected or known blood cancer in Australia and New Zealand. The ALLG also collects and stores donated tissue samples from patients in a biorepository. Clinicians, researchers and health service providers apply to the ALLG to access the data and tissue samples in order to find better ways to predict, treat or even prevent disease.

Lay Summary
The ALLG AML Registry will facilitate a number of functions associated with AML trials and thereby promote improved outcomes for patients. Some of the advantages to the establishment of the Registry are:

1. The Registry will enhance patient participation in clinical trials by facilitating cross referral of patients to sites that are running other ALLG AML trials.

2. The clear detail of tests to be conducted at baseline will align with ALLG AML clinical trial screening procedures to minimise burden on the patient and to ensure that the correct samples are collected, thus maximising participation in ALLG AML clinical trials.

3. The registry will also facilitate the implementation of central review and central testing of factors critical to the successful treatment of AML, and enhance consistency in clinical trial populations to ensure trial results are meaningful.

4. The collection of samples for the ALLG Tissue Bank, coupled with details and times of treatment and response status, provides a valuable resource not only for researchers wishing to access these samples through the ALLG Tissue Bank, but also allows stored tissue to be analysed for new prognostic markers and molecular subtypes to ensure that results from ongoing and completed clinical trials can be analysed incorporating stratification of these new entities. This ensures clinical trial results remain relevant in the current landscape of AML treatment.

WA Trial Sites

Fiona Stanley Hospital Haematology
Ph. (08) 08 6152 6540

RPH Haematology
Ph. (08) 9224 2405
Haematology Care Centre
Sir Charles Gairdner Hospital
Ph. (08) 6383 3207
Fax (08) 9346 4432
Email: louise.hay@health.wa.gov.au

Links
US National Library of Medicine

Acknowledgements: US National Library of Medicine
Acute Lymphoblastic Leukaemia

**ALL6 Study**

**Registered Title**
A phase II trial of an intensive pediatric protocol incorporating post-induction stratification based on minimal residual disease levels for the treatment of adolescents aged 15 years and above, and young adults aged up to 40 years, with newly diagnosed acute lymphoblastic leukaemia (ALL).

**Purpose**
In this national study which will be carried out in a large number of Australian adult hospitals, a childhood ALL treatment program, which is currently being used in Children's hospitals in a separate national study, will be adapted for use in ALL patients aged 15 to 40 years, in order to find out whether this treatment can given as effectively as it can in young children.

**Lay Summary**
Patients will be started on a treatment protocol originally devised in Germany for use in children, and now used widely in other countries, including Australia. The first 2 months of treatment will be standard and given to all patients. This will involve being given several different chemotherapy drugs, according to a fixed schedule. Following this, treatment will depend on certain characteristics of the patient's leukaemia at diagnosis, and on the patient's response to the first 2 months of treatment.

In the protocol that will be used in this study, the treatment given after the initial 2 months will be determined, as it is with children, by the risk group calculated for each individual patient. People who fit into Standard and Medium risk groups will be treated according to a particular protocol designed for children in these risk categories, while people who are shown to have high, medium high or very high risk disease will be given more intensive treatment, usually including bone marrow transplantation.

**WA Trial Sites**

Haematology Care Centre  
Sir Charles Gairdner Hospital  
Ph. (08) 6383 3207  
Fax (08) 9346 4432  
Email: louise.hay@health.wa.gov.au

**Links**
Australian New Zealand Clinical Trials Registry
Chronic Lymphocytic Leukaemia

ASCEND Study

Registered Title A Randomized, Multicenter, Open-Label, Phase 3 Study of Acalabrutinib (ACP-196) Versus Investigator’s Choice of Either Idelalisib Plus Rituximab or Bendamustine Plus Rituximab in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia.

Purpose This study is designed to evaluate the efficacy of acalabrutinib compared with rituximab in combination with idelalisib or bendamustine in previously treated subjects with chronic lymphocytic leukemia (CLL).

Lay Summary N/A

WA Trial Sites

Fiona Stanley Hospital Haematology Ph. (08) 08 6152 6540

Perth Blood Institute 3/95 Monash Avenue, Nedlands, WA info@pbi.org.au Ph. (08) 9200 4904

Links US National Library of Medicine

Acknowledgements: US National Library of Medicine
Care After Lymphoma

Registered Title
Care After Lymphoma (CALy) Trial: A randomised controlled trial testing the effect of a pilot nurse-led lymphoma survivorship clinic with lymphoma survivors to decrease the number of unmet informational needs to reduce anxiety, stress and to increase self-empowerment.

Purpose
This project aims to develop and test a nurse-led model of survivorship care for lymphoma survivors.

Lay Summary
Participants will be randomly allocated to one of two groups. Participants in one group will continue to receive usual follow-up care with their haematologist. Participants in the other group will take part in an evidenced-based survivorship clinic that will provide tailored care to patients who have completed active treatment. The intervention will involve three 1 hour face-to-face structured interviews that will occur over a 6 month period. These will involve discussion and delivery of a survivorship care plan, treatment summary and resource pack. Participants in both groups will be asked to complete a number of questionnaires at baseline, 3 months and 6 months in order to evaluate unmet informational and practical needs, depression, anxiety, stress, coping and self-empowerment. The findings from this study will make a significant contribution to the planning and delivery of survivorship care.

WA Trial Sites
Haematology Care Centre
Sir Charles Gairdner Hospital
Ph. (08) 6383 3207
Fax (08) 9346 4432
Email: louise.hay@health.wa.gov.au

Links
Australian New Zealand Clinical Trials Registry

Acknowledgements: Australian New Zealand Clinical Trials Registry
## CLL07 CAMMERAY Trial

### Registered Title
An Australasian, phase II, multicentre, randomised, study investigating safety and efficacy for dose reduced fludarabine, cyclophosphamide and iv obinutuzumab (G-FC3) versus oral chlorambucil and iv obinutuzumab (G-Clb) in previously untreated, comorbid (CIRS score greater than or equal to 6), elderly (greater than or equal to 65 years old) patients with chronic lymphocytic leukaemia (CLL).

### Purpose
The study is evaluating the efficacy and safety for dose reduced fludarabine, cyclophosphamide and intravenous obinutuzumab (G-FC3) versus oral chlorambucil and intravenous obinutuzumab (G-Clb) in previously untreated, comorbid, elderly patients with chronic lymphocytic leukaemia (CLL).

### Lay Summary
N/A

### WA Trial Sites
Haematology Care Centre  
Sir Charles Gairdner Hospital  
Ph. (08) 6383 3207  
Fax (08) 9346 4432  
Email: louise.hay@health.wa.gov.au

### Links
[Australian New Zealand Clinical Trials Registry](#)
CLL6 RESIDUUM Trial

Registered Title  An Australasian, Phase III, Multicentre, Randomised Trial Comparing Lenalidomide Consolidation Vs No Consolidation in Patients With Chronic Lymphocytic Leukaemia (CLL) and Residual Disease Following Induction Chemotherapy.

Purpose  his study aims to determine if lenalidomide is capable of extending remission duration in patients with CLL who have detectable residual disease following induction chemotherapy.

Lay Summary  Lenalidomide is active against chemotherapy resistant CLL and may be effective in improving response status following chemotherapy.

WA Trial Sites

Haematology Care Centre
Sir Charles Gairdner Hospital
Ph. (08) 6383 3207
Fax (08) 9346 4432
Email: louise.hay@health.wa.gov.au

Links  Australian New Zealand Clinical Trials Registry
VENICE-II Study

Registered Title  Open-Label, Single Arm, Phase 3b, Multi-Center Study Evaluating the Impact of Venetoclax on the Quality of Life of Relapsed/Refractory Subjects With Chronic Lymphocytic Leukemia (CLL) Including Those With the 17p Deletion or TP53 Mutation OR Those Who Have Received Prior Treatment With B-Cell Receptor Inhibitor.

Purpose  The purpose of this open-label, single-arm study is to evaluate the impact of venetoclax on the quality of life of participants with chronic lymphocytic leukemia (CLL; a type of cancer affecting the blood and the bone marrow) including those with the 17p deletion or TP53 mutation (local lab assessed) OR in CLL participants who have received prior B-Cell Receptor Inhibitor (BCRI) therapy.

Lay Summary  A Study Evaluating Venetoclax in Subjects With Chronic Lymphocytic Leukemia Whose Cancer Has Come Back or Who Had No Response to Previous Cancer Treatments Including Subjects Missing Part of Their Chromosome 17, or TP53 Gene Mutation; or Who Received Prior Treatment With a B-Cell Receptor Inhibitor.

WA Trial Sites

Perth Blood Institute
3/95 Monash Avenue, Nedlands, WA
info@pbi.org.au
Ph. (08) 9200 4904

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
Chronic Myeloid Leukaemia

Care After Lymphoma

Registered Title  Care After Lymphoma (CALy) Trial: A randomised controlled trial testing the effect of a pilot nurse-led lymphoma survivorship clinic with lymphoma survivors to decrease the number of unmet informational needs to reduce anxiety, stress and to increase self-empowerment.

Purpose  This project aims to develop and test a nurse-led model of survivorship care for lymphoma survivors.

Lay Summary  Participants will be randomly allocated to one of two groups. Participants in one group will continue to receive usual follow-up care with their haematologist. Participants in the other group will take part in an evidenced-based survivorship clinic that will provide tailored care to patients who have completed active treatment. The intervention will involve three 1 hour face-to-face structured interviews that will occur over a 6 month period. These will involve discussion and delivery of a survivorship care plan, treatment summary and resource pack. Participants in both groups will be asked to complete a number of questionnaires at baseline, 3 months and 6 months in order to evaluate unmet informational and practical needs, depression, anxiety, stress, coping and self-empowerment. The findings from this study will make a significant contribution to the planning and delivery of survivorship care.

WA Trial Sites

Haematology Care Centre  
Sir Charles Gairdner Hospital  
Ph. (08) 6383 3207  
Fax (08) 9346 4432  
Email: louise.hay@health.wa.gov.au

Links  
Australian New Zealand Clinical Trials Registry

Acknowledgements: Australian New Zealand Clinical Trials Registry
Hodgkin's Lymphoma

There are currently no Hodgkin's Lymphoma trials available for listing.
Non-Hodgkin's Lymphoma

ACE-LY-308 Mantle Cell Lymphoma

Registered Title
A Phase 3, Randomized, Double-blind, Placebo-controlled, Multicenter Study of Bendamustine and Rituximab (BR) Alone Versus in Combination with Acalabrutinib (ACP-196) in Subjects with Previously Untreated Mantle Cell Lymphoma.

Purpose
This study is evaluating the efficacy of acalabrutinib in combination with bendamustine and rituximab (BR) compared with placebo plus BR in subjects with previously untreated mantle cell lymphoma.

Lay Summary
N/A

WA Trial Sites

Fiona Stanley Hospital Haematology
Ph. (08) 08 6152 6540

Perth Blood Institute
3/95 Monash Avenue, Nedlands, WA
info@pbi.org.au
Ph. (08) 9200 4904

Haematology Care Centre
Sir Charles Gairdner Hospital
Ph. (08) 6383 3207
Fax (08) 9346 4432
Email: louise.hay@health.wa.gov.au

Links
US National Library of Medicine

Acknowledgements: US National Library of Medicine
ALLG NHL29 IRiC - Diffuse Large B Cell Lymphoma

Registered Title     A Phase II Study of Ibrutinib, Rituximab and mini-CHOP therapy in very elderly patients with newly diagnosed Diffuse Large B Cell Lymphoma (DLBCL).

Purpose             This study will evaluate the deliverability and efficacy of Ibrutinib-R-mini-CHOP chemotherapy in elderly patients with newly diagnosed diffuse large B-cell lymphoma (DLBCL). Who is it for? You may be eligible to join this study if you are aged 75 years or above and have been newly diagnosed with DLBCL for which you have received no prior treatment (excluding prednisone). Study details: All participants in this study will be treated with a chemotherapy regime known as Ibrutinib-R-mini-CHOP. This will include treatment with the drugs prednisone (orally), ibrutinib (orally), rituximab intravenously ((IV) - i.e. administered directly into the vein), cyclophosphamide IV, doxorubicin IV, vincristine IV and Pegfilgrastim G-CSF (subcutaneous injection). Treatment duration will be for up to 8 x 28 day cycles as tolerated. All participants will be regularly assessed for a minimum of 2 years in order to evaluate the safety, toxicity and effectiveness of treatment.

Lay Summary          N/A

WA Trial Sites

Haematology Care Centre
Sir Charles Gairdner Hospital
Ph. (08) 6383 3207
Fax (08) 9346 4432
Email: louise.hay@health.wa.gov.au

Links
Australian New Zealand Clinical Trials Registry
B-MIND MOR208C204 Diffuse Large B Cell Lymphoma Study

Registered Title  A Phase 2/3, Randomised, Multicentre Study of MOR208 With Bendamustine Versus Rituximab With Bendamustine in Patients With Relapsed or Refractory Diffuse Large B-Cell Lymphoma (R-R DLBCL) Who Are Not Eligible for High-Dose Chemotherapy (HDC) and Autologous Stem-Cell Transplantation (ASCT).

Purpose  The purpose of the study is to compare the safety and efficacy of MOR208 with BEN versus RTX with BEN in adult patients with relapsed of refractory DLBCL.

Lay Summary  This is a randomised, two-arm, multicentre, open-label phase II/III efficacy and safety study of MOR208 in combination with BEN versus RTX in combination with BEN given to adult patients who have relapsed after or are refractory to at least one but no more than three prior systemic therapies and have failed, or are not candidates for HDC and ASCT, and have thus exhausted their therapeutic options of demonstrated clinical benefit. At least one prior therapy line must have included a CD20-targeted therapy.

WA Trial Sites  
Perth Blood Institute  
3/95 Monash Avenue, Nedlands, WA  
info@pbi.org.au  
Ph. (08) 9200 4904

Links  
US National Library of Medicine

Acknowledgements: US National Library of Medicine
Study of the Safety and Pharmacokinetics of BGB-3111 in Subjects With B-Cell Lymphoid Malignancies

Registered Title
This is a Phase I, Open Label, Multiple Dose, Dose Escalation Study and Expansion study to Investigate the Safety and Pharmacokinetics of the BTK Inhibitor BGB-3111 in Subjects with B-Cell Lymphoid Malignancies.

Purpose
To investigate the safety and action of the study drug BGB-3111 in Subjects with B-Cell Lymphoid Malignancies.

Lay Summary
This is a first-in-human study of a new drug called BGB-3111 to see what effects (good and bad) it has on you and your cancer.

The purpose of this study is to (1) determine if this drug is safe for human use, and (2) find the most effective dose of this drug as a treatment for your disease.

A key purpose of this part of the study is to determine whether once or twice daily dosing is better at targeting the cancer.

BGB-3111 is an experimental treatment. This means that it is not an approved treatment for B-Cell Lymphoid Malignancies in Australia.

WA Trial Sites
Haematology Care Centre
Sir Charles Gairdner Hospital
Ph. (08) 6383 3207
Fax (08) 9346 4432
Email: louise.hay@health.wa.gov.au

Links
US National Library of Medicine

Acknowledgements: US National Library of Medicine
BGB 3111 in Combination With Obinutuzumab in Subjects With B-Cell Lymphoid Malignancies

Registered Title  A Phase 1b Study to Assess Safety, Tolerability and Antitumor Activity of the Combination of BGB 3111 With Obinutuzumab in Subjects With B-Cell Lymphoid Malignancies.

Purpose  This study is evaluating the safety and preliminary efficacy of BGB-3111 in combination with obinutuzumab in subjects with B-cell lymphoid malignancies.

Lay Summary  N/A

WA Trial Sites  

[Image of Royal Perth Hospital]

RPH Haematology
Ph. (08) 9224 2405

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
BGB-3111 in Combination With BGB-A317 in Subjects With B-cell Malignancies

Registered Title  A Phase 1b, Open Label, Multiple Dose, Dose Escalation and Expansion Study to Assess Safety, Tolerability and Antitumor Activities of the Combination of BGB-3111 with BGB-A317 in Subjects with B-Cell Lymphoid Malignancies.

Purpose  This is a Phase 1b study to evaluate safety, tolerability, and preliminary efficacy of BGB-3111 in combination with BGB-A317 in subjects with B-cell malignancies, including relapsed/refractory chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), mantle cell lymphoma (MCL), Waldenström’s Macroglobulinemia (WM), non-germinal center B-cell (non-GCB) diffuse large B-cell lymphoma (DLBCL), follicular lymphoma (FL), marginal zone lymphoma (MZL), hairy cell leukemia (HCL), transformed FL, and Richter’s transformation.

Lay Summary  N/A

WA Trial Sites

Haematology Care Centre
Sir Charles Gairdner Hospital
Ph. (08) 6383 3207
Fax (08) 9346 4432
Email: louise.hay@health.wa.gov.au

Links
US National Library of Medicine

Acknowledgements: US National Library of Medicine
**BGB-311-204 Long term extension study**

**Registered Title**  
An Open-label Long-Term Extension Study of Bruton’s Tyrosine Kinase (BTK) inhibitor BGB-3111 in B Cell malignancies.

**Purpose**  
To evaluate the long-term safety of BGB-3111 in subjects with B cell malignancies who participated in any BGB-3111 clinical trial.

**Lay Summary**  
N/A

**WA Trial Sites**

Haematology Care Centre  
Sir Charles Gairdner Hospital  
Ph. (08) 6383 3207  
Fax (08) 9346 4432  
Email: louise.hay@health.wa.gov.au

**Links**  
N/A
B-MIND MOR208C204 Diffuse Large B Cell Lymphoma Study

**Registered Title**  
A Phase III, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Copanlisib in Combination With Rituximab in Patients with Relapsed Indolent B-cell Non-Hodgkin's Lymphoma (iNHL) - CHRONOS-3.

**Purpose**  
The purpose of this study is to evaluate whether copanlisib in combination with rituximab is superior to placebo in combination with rituximab in prolonging progression free survival (PFS) in patients with relapsed iNHL who have received one or more lines of treatment, including rituximab. Purpose of the study is also to evaluate the safety and tolerability of copanlisib.

**Lay Summary**  
N/A

**WA Trial Sites**

Perth Blood Institute  
3/95 Monash Avenue, Nedlands, WA  
info@pbi.org.au  
Ph. (08) 9200 4904

**Links**  

Acknowledgements: US National Library of Medicine
**CHRONOS-4 Indolent B-cell Non-Hodgkin's Lymphoma**

**Registered Title**

**Purpose**
The purposes of this study are to evaluate whether copanlisib in combination with standard immunochemotherapy, is superior to standard immunochemotherapy in prolonging progression-free survival, in patients with relapsed indolent non-Hodgkin’s lymphoma, who have received one or more lines of treatment, including rituximab and alkylating agents. The study has two parts: safety run-in / dose finding part and a phase III placebo-controlled part. The study will start with the safety run-in part, where two dose levels of copanlisib will be tested for safety and tolerability. This will determine the dose to be administered in phase III part. In the phase III part patients who meet the eligibility criteria will be randomly assigned to copanlisib or placebo plus R-CHOP or R-Bendamustine depending on their previous medical history.

**Lay Summary**
N/A

**WA Trial Sites**
Fiona Stanley Hospital Haematology
Ph. (08) 08 6152 6540

**Links**

Acknowledgements: US National Library of Medicine
Gilead 1580 - Follicular Lymphoma

Registered Title  Dose Optimization Study of Idelalisib in Follicular Lymphoma (FL) and Small Lymphocytic Lymphoma.

Purpose  The study will evaluate the safety, efficacy, and PK of idelalisib in subjects randomized to either 150 mg BID or 100 mg of idelalisib BID. The target population comprises adults with previously treated relapsed FL who have measurable lymphadenopathy and require therapy according to standard response criteria.

Lay Summary  N/A

WA Trial Sites

RPH Haematology
Ph. (08) 9224 2405

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
**Jasmine CD20 Positive B-Cell Non-Hodgkin Lymphoma Study**

**Registered Title**  

**Purpose**  
This trial is designed to determine what effects the human body has on the investigational medicine, ABP 798, and what effects the body has on the investigational medicine after you have been given it, and if this is comparable to what is seen for the licensed medicine, rituximab, in patients with CD 20 positive B-cell non Hodgkin lymphoma. This study will assess if the investigational medicine is safe and effective in treating CD 20 positive B-cell non Hodgkin lymphoma.

**Lay Summary**  
N/A

**WA Trial Sites**

Fiona Stanley Hospital Haematology  
Ph. (08) 08 6152 6540

**Links**

[US National Library of Medicine](#)

Acknowledgements: US National Library of Medicine
Verdi B-Cell Non Hodgkin Lymphoma Study

Registered Title  A Phase 2/3 Multi-center Study to Evaluate the Safety and Efficacy of Blinatumomab in Subjects with Relapsed/Refractory Aggressive B-Cell Non Hodgkin Lymphoma.

Purpose  This is a phase 2/3 open label, multicenter trial testing blinatumomab monotherapy for the treatment of subjects with Relapsed/Refractory (R/R) aggressive B-NHL not achieving CMR after 2 cycles of standard platinum-based chemotherapy regimens administered as S1. This study incorporates multiple interim analyses for futility, efficacy, and unblinded sample-size re-estimation. In the phase 3 part of the study, blinatumomab will be compared to Investigator's Choice chemotherapy.

Lay Summary  N/A

WA Trial Sites

Fiona Stanley Hospital Haematology
Ph. (08) 08 6152 6540

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
Multiple Myeloma

BELLINI M14-031 Study

Registered Title  A Phase 3, Multicenter, Randomized, Double Blind Study of Bortezomib and Dexamethasone in Combination With Either Venetoclax or Placebo in Subjects With Relapsed or Refractory Multiple Myeloma Who Are Sensitive or Naive to Proteasome Inhibitors.

Purpose  This is a Phase 3, multicenter, randomized, double blind, placebo-controlled study evaluating the efficacy and safety of venetoclax plus bortezomib and dexamethasone in subjects with relapsed or refractory multiple myeloma who are considered sensitive or naive to proteasome inhibitors and received 1 to 3 prior lines of therapy for multiple myeloma.

Lay Summary  N/A

WA Trial Sites

Fiona Stanley Hospital Haematology
Ph. (08) 08 6152 6540

Perth Blood Institute
3/95 Monash Avenue, Nedlands, WA
info@pbi.org.au
Ph. (08) 9200 4904

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
INTREPID-1 Study

Registered Title  A Phase 1b Study Evaluating the Safety, Tolerability, Pharmacokinetics and Efficacy of Oprozomib in Combination with Pomalidomide and Dexamethasone in Subjects with Relapsed or Refractory Multiple Myeloma.

Purpose  A study evaluating two new formulations of oprozomib plus pomalidomide and dexamethasone in patients with relapsed refractory multiple myeloma.

Lay Summary  N/A

WA Trial Sites  Fiona Stanley Hospital Haematology
Ph. (08) 08 6152 6540

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
WA Myeloma and Related Diseases Registry

Registered Title Myeloma and Related Diseases Registry.

Purpose Long-term patient follow-up and review of clinical (safety and efficacy) and correlative data outside of clinical trials will be highly valuable in informing optimal treatment strategies for myeloma and its related diseases. Clinical registries provide a useful mechanism to collect data on patterns of treatment and variation in outcomes (both survival and quality of life). They enable clinicians to benchmark against national and international standards and allow evaluation of the translation of advances in therapy (such as introduction in new targeted therapies) into long-term outcomes outside the setting of clinical trials.

Lay Summary N/A

WA Trial Sites

Haematology Care Centre
Sir Charles Gairdner Hospital
Ph. (08) 6383 3207
Fax (08) 9346 4432
Email: louise.hay@health.wa.gov.au

Links N/A
Bone Marrow Transplant

CTTWA Phase II MSC Trial

Registered Title  A Phase 2 Trial of Standard of Care Treatment Versus Mesenchymal Stromal Cell Therapy Together With Standard of Care for the Treatment of de Novo Acute Graft Versus Host Disease Following Allogeneic Bone Marrow Transplantation.

Purpose  A randomised study of corticosteroid therapy with or without mesenchymal stromal cell therapy for newly diagnosed acute graft versus host disease after bone marrow transplantation or donor lymphocyte therapy. It is hypothesised that mesenchymal stromal cell therapy will be superior.

Lay Summary  Standard of care treatment versus mesenchymal stromal cell therapy together with standard of care treatment for the treatment of de novo grades 2-4 acute graft versus host disease following allogeneic bone marrow transplantation.

WA Trial Sites

Fiona Stanley Hospital Haematology
Ph. (08) 08 6152 6540

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
Myelodysplastic Syndrome

CC-486-MDS-006 Myelodysplastic Disorders Study

Registered Title  A Phase 2, International, Multicenter, Randomized, Open-label, Parallel Group to Evaluate the Efficacy and Safety of Cc-486 (Oral Azacitidine) Alone in Combination With Durvalumab (MEDI4736) in Subjects With Myelodysplastic Syndromes Who Fail to Achieve an Objective Response to Treatment With Azacitidine for Injection or Decitabine.

Purpose  Evaluate the safety and efficacy of CC-486 and Durvalumab in Subjects with Myelodysplastic Syndromes who failed to achieve an objective response post iHMA treatment.

Lay Summary  N/A

WA Trial Sites  

Royal Perth Hospital  
RPH Haematology  
Ph. (08) 9224 2405

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
**MDS-MSC01 Myelodysplastic Disorders Study**

<table>
<thead>
<tr>
<th><strong>Registered Title</strong></th>
<th>Mesenchymal stromal cells as therapy for Myelodysplasia of Low and Intermediate IPSS prognostic risk.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Lay Summary</strong></td>
<td>Myelodysplasia is a malignant disease of bone marrow failure. It occurs due to abnormal production of blood components (cells). It presents with low blood counts (anaemia, thrombocytopenia, neutropenia) and its complications include fatigue, bleeding, infections and transformation to acute myeloid leukaemia. Life expectancy is significantly reduced by this disease. Prognosis in MDS is classified from low to high risk based on the IPSS (WHO, 2001) which better predicts overall survival and progression to acute leukaemia. Low and intermediate-1 risk patients with MDS (considered for this study) would have median overall survival of 3.4-5.7 years. Standard care for patients with MDS is supportive (i.e. blood transfusions, treatment of infections). There are significant impacts to quality of life for this disorder due to frequent hospital presentations, transfusion, infections and a lack of treatment options.</td>
</tr>
</tbody>
</table>

**WA Trial Sites**

- Royal Perth Hospital
  - RPH Haematology
  - Ph. (08) 9224 2405

**Links**

- N/A
Other Haematology Trials

ALXN-1210-PNH-301 Paroxysmal Nocturnal Hemoglobinuria Study

Registered Title  A Phase 3, Randomized, Open-Label, Active-Controlled Study of ALXN1210 Versus Eculizumab in Complement Inhibitor-Naive Adult Patients With Paroxysmal Nocturnal Hemoglobinuria (PNH).

Purpose  The purpose of this study is to assess ALXN1210 compared to eculizumab in adult patients with PNH who have not previously used a complement inhibitor.

Lay Summary  N/A

WA Trial Sites

Perth Blood Institute
3/95 Monash Avenue, Nedlands, WA
info@pbi.org.au
Ph. (08) 9200 4904

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
Aplastic Anaemia Registry

Registered Title
Aplastic Anaemia Registry (AA).

Purpose
The aims of the Aplastic Anaemia Registry are to: 1) Better define the incidence of AA in Australia; 2) Provide information on the range of therapeutic strategies being employed in the treatment of AA patients, including IST, HSCT and supportive care; 3) Explore factors influencing clinical outcomes; 4) Investigate the relationship of PNH clones to progress of disease and response to therapy; 5) Better define optimal management of AA patients Inform and inspire future hypothesis-driven research in this area.

Lay Summary
N/A

WA Trial Sites

Royal Perth Hospital
Ph. (08) 9224 2405

Haematology Care Centre
Sir Charles Gairdner Hospital
Ph. (08) 6383 3207
Fax (08) 9346 4432
Email: louise.hay@health.wa.gov.au

Links
N/A
### APMAT1 Microangiopathic Thrombocytopenia Study

<table>
<thead>
<tr>
<th><strong>Registered Title</strong></th>
<th>A Multi-centre, Observational Study by the Asian-Pacific Microangiopathic Thrombocytopenia (APMAT) Network To Determine The Clinical Characteristics, Laboratory Features, Treatments, and Clinical Outcomes in Patients with Microangiopathic Thrombocytopenia.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>This is an observational study of patients who have previously been diagnosed and treated for Microangiopathic Thrombocytopenia (MAT). The study will collect clinical and laboratory data to assess the disease characteristics, laboratory features, treatments, and clinical outcome.</td>
</tr>
<tr>
<td><strong>Lay Summary</strong></td>
<td>N/A</td>
</tr>
</tbody>
</table>
| **WA Trial Sites**   | ![Perth Blood Institute](image)  
Perth Blood Institute  
3/95 Monash Avenue, Nedlands, WA  
info@pbi.org.au  
Ph. (08) 9200 4904 |
| **Links**            | [Australian New Zealand Clinical Trials Registry](#) |
BGB-3111-302 Waldenstrom’s Macroglobulinemia Study

Registered Title  
A Phase 3, Randomized, Open-Label, Multicenter Study Comparing the Efficacy and Safety of the Bruton’s Tyrosine Kinase (BTK) Inhibitors BGB-3111 and Ibrutinib in Subjects with Waldenstrom’s Macroglobulinemia (WM).

Purpose  
This open-label, randomized study will compare the efficacy and safety of the Bruton’s Tyrosine Kinase (BTK) inhibitors BGB-3111 and ibrutinib in subjects with Waldenstrom’s Macroglobulinemia who require therapy. Subjects will have baseline bone marrow samples assayed for sequencing of the MYD88 gene. Approximately 150 subjects with the MYD88 mutation will be enrolled onto Cohort 1 and randomized to receive 160 mg BGB-3111 PO BID (treatment Arm A) or to receive 420 mg ibrutinib QD (treatment Arm B) until disease progression or unacceptable toxicity. Subjects with MYD88 wild type will be enrolled to Cohort 2 and will receive 160 mg BGB-3111 PO BID (treatment Arm C) until disease progression or unacceptable toxicity.

Lay Summary  
N/A

WA Trial Sites

Haematology Care Centre
Sir Charles Gairdner Hospital
Ph. (08) 6383 3207
Fax (08) 9346 4432
Email: louise.hay@health.wa.gov.au

Links  
US National Library of Medicine
A Phase 3 Randomized, Controlled, Open-label, Multicenter, Safety and Efficacy Study of Dexamethasone Plus MLN9708 or Physician’s Choice of Treatment Administered to Patients with Relapsed or Refractory Systemic Light Chain (AL) Amyloidosis.

The purpose of this study is to find out if MLN9708 plus dexamethasone improves against systemic light chain amyloidosis better than the physician’s choice chemotherapy treatment. Physician’s choice chemotherapy treatment is a treatment regimen that is commonly used to treat amyloidosis patients. The study will also determine if MLN9708 plus dexamethasone can change the chance that the amyloidosis will cause heart and/or kidneys to begin to work poorly needing care in the hospital or of dying.

Another purpose of this study is to see how differences in DNA, RNA and proteins related to the disease may influence the way people respond to MLN9708. This information may be used by the Sponsor of this study, Millennium Pharmaceuticals, its agents and its affiliated companies for research related to analysis and development of MLN9708 and associated disease states, for example:

- to develop a better understanding of how people’s genes affect the safety and effectiveness of MLN9708
- to help develop new ways to monitor and treat cancer
- to generate information needed for research, development and regulatory approval of diagnostic tests related to diseases or conditions that MLN9708 might treat

This is a phase 3, randomized, controlled, open-label, multicenter study of the oral formulation of dexamethasone plus MLN9708 compared with treatment chosen by the investigator from a prespecified list of regimens available in clinical practice. Treatment options will include: dexamethasone alone, dexamethasone plus an alkylating agent (melphalan or cyclophosphamide), or dexamethasone plus an immunomodulatory drug (IMiD, thalidomide or lenalidomide) in patients with relapsed or refractory AL amyloidosis. Crossover to the investigational treatment arm is not permitted during participation in this study.

Haematology Care Centre
Sir Charles Gairdner Hospital
Ph. (08) 6383 3207
Fax (08) 9346 4432
Email: louise.hay@health.wa.gov.au

Links
US National Library of Medicine
HERCULES Acquired Thrombotic Thrombocytopenic Purpura Study

Registered Title  A Phase III Double-blind, Randomized, Parallel Group, Multicenter Placebo-controlled Trial to Study the Efficacy and Safety of Caplacizumab in Patients With Acquired Thrombotic Thrombocytopenic Purpura.

Purpose  The study is a phase III, double blind, placebo-controlled, randomized study to evaluate the efficacy and safety of caplacizumab treatment in more rapidly curtailing ongoing microvascular thrombosis when administered in addition to standard of care treatment in subjects with an acute episode of acquired TTP.

Lay Summary  N/A

WA Trial Sites

RPH Haematology
Ph. (08) 9224 2405

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
MEPO Study

Registered Title
Mepolizumab Compassionate Use Supply Program (SB240563.MHE104317).

Purpose
The purpose of this programme is to provide a treatment option to patients with life-threatening Hypereosinophilic Syndrome (HES) whose symptoms are not controlled with other therapies and to provide continued access to mepolizumab for subjects who received clinical benefit in Study MHE100901 following termination of the study.

Lay Summary
Eligible patients will receive a supply of Mepolizumab for monthly infusions with up to 10mg/kg (maximum dose 750mg or 10mg/kg if body weight less than 45kg) Mepolizumab IV for an initial three months of treatment. The duration and frequency of additional treatment with Mepolizumab will be determined based on the subject’s response to the initial three months of treatment as demonstrated by significant lowering of eosinophil level and/or decreased signs and symptoms of HES.

WA Trial Sites

Haematology Care Centre
Sir Charles Gairdner Hospital
Ph. (08) 6383 3207
Fax (08) 9346 4432
Email: louise.hay@health.wa.gov.au

Links
US National Library of Medicine

Acknowledgements: US National Library of Medicine
MPN01 Registry

Registered Title
Australasian Leukaemia and Lymphoma Group Myeloproliferative Neoplasms Registry.

Purpose
The aim of this registry is collect information on patients in Australia and New Zealand who have been diagnosed with a myeloproliferative neoplasm (polycythaemia vera, essential thrombocythaemia, primary myelofibrosis, chronic eosinophilic leukaemia) or a related disorder (hypereosinophilic syndrome, refractory anaemia with ringed sideroblasts associated with a marked thrombocytosis) and to understand the nature of the disease in the local area.

Lay Summary
The registry is an observational study and participating does not mandate the performance of investigations and does not recommend any treatment. The registry will collect information at the time the blood disorder was diagnosed which will include information about the haematological disease, the presence of comorbidities (other illnesses), family history of blood disorders, complications present in the disease and any therapies started.

More information will be collected for the registry every 12 months on the progress of the disease, its therapy and any complications that may have developed for as long as the registry remains open.

Patients will be offered the opportunity to complete a quality-of-life assessment (MPNSAF: myeloproliferative neoplasm symptom assessment form) within the first three months of diagnosis and on an annual basis.

There will not be any requirement to attend any additional appointments through participation in the MPN01 registry.

Patients will be asked to provide consent to obtain additional blood, bone marrow & saliva samples if they wish to take part in the optional scientific studies.

WA Trial Sites
Haematology Care Centre
Sir Charles Gairdner Hospital
Ph. (08) 6383 3207
Fax (08) 9346 4432
Email: louise.hay@health.wa.gov.au

Links
Australian New Zealand Clinical Trials Registry
PNH Registry

Registered Title
A global, observational, non-interventional study collecting effectiveness, safety and quality of life data on patients with Paroxysmal Nocturnal Haemoglobinuria (PNH) Disease.

Purpose
The Registry will evaluate safety data specific to the use of Soliris, and will collect data to characterize the progression of PNH as well as clinical outcomes, mortality and morbidity in Soliris and non-Soliris treated patients. The registry also aims to raise PNH awareness in the medical community and subject/potential subject population.

Lay Summary
The registry will enrol patients treated with Soliris for any reason, as well as patients with PNH. Clinical data will be collected from patients enrolled in this study. Participants will also be required to complete six monthly quality of life questionnaires.

WA Trial Sites

Haematology Care Centre
Sir Charles Gairdner Hospital
Ph. (08) 6383 3207
Fax (08) 9346 4432
Email: louise.hay@health.wa.gov.au

Fiona Stanley Hospital Haematology
Ph. (08) 08 6152 6540

Perth Blood Institute
3/95 Monash Avenue, Nedlands, WA
info@pbi.org.au
Ph. (08) 9200 4904

Links
PNH Registry website
US National Library of Medicine
TTP Registry

Registered Title
Thrombotic Thrombocytopenic Purpura (TTP) Registry.

Purpose
The aims of the TTP Registry are to:

- Better define the incidence, natural history, specific clinical characteristics, and clinical outcome of patients with TTP and HUS.
- Provide information on the range of therapeutic strategies employed in the treatment of TTP and HUS patients.
- Explore factors influencing clinical outcomes.
- Help define optimal management of patients with TTP and HUS.
- Inform and inspire future hypothesis-driven research in this area.

Lay Summary
The TTP Registry will be a register of patients who develop TTP in any clinical setting. Clinical data collection will be undertaken by clinicians in specialist units at participating hospitals. Data management and analysis will be undertaken by the Department of Epidemiology and Preventive Medicine (DEPM), Monash University and interpreted with the input of Transfusion Medicine Specialists at ARCBS and specialist clinicians on the Registry Steering Committee. The Registry began collecting data in December 2008.

Patients are identified either by the treating clinician, or by ARCBS clinicians as a result of referral for provision of blood components for therapy. Patient liaison and registration will take place in participating hospitals. Recruitment strategies take advantage of the fact that all patients will require blood component therapy provided by ARCBS, and patients are largely managed by a small group of specialised clinicians in a limited number of major centres with apheresis facilities. Registry staff will maintain close interaction with key individuals working in relevant hospital clinical care areas to ensure notification of all patients.

WA Trial Sites

Haematology Care Centre
Sir Charles Gairdner Hospital
Ph. (08) 6383 3207
Fax (08) 9346 4432
Email: louise.hay@health.wa.gov.au

Links
N/A
CA209-651 Study

Registered Title  An Open Label, Randomized, Two Arm Phase III Study of Nivolumab in Combination With Ipilimumab Versus Extreme Study Regimen (Cetuximab + Cisplatin/Carboplatin + Fluorouracil) as First Line Therapy in Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN).

Purpose  The main purpose of this study is to compare nivolumab and ipilimumab with the Extreme study regimen as first line treatment in patients with recurrent or metastatic squamous cell of the head and neck cancer.

Lay Summary  N/A

WA Trial Sites

SCGH Medical Oncology
Ph. (08) 6383 3000

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
HPV Oropharynx (TROG 12.01)

Registered Title
HPV Oropharynx: A Randomised Trial of Weekly Cetuximab and Radiation versus Weekly Cisplatin and Radiation in Good Prognosis Locoregionally Advanced HPV-Associated Oropharyngeal Squamous Cell Carcinoma (TROG 12.01).

Purpose
This study aims to compare radiation treatment (RT) combined with either cetuximab or cisplatin in patients with locoregionally advanced HPV positive oropharyngeal squamous cell carcinoma (OPSCC) (located at the base of tongue or tonsil).

The main aim of the study is to compare the severity of symptoms between weekly cisplatin and RT versus weekly cetuximab and RT.

Lay Summary
A standard treatment for patients with cancer of the base of tongue or tonsil that is associated with HPV is radiation given with a chemotherapy drug called cisplatin. Cisplatin may be given in high doses every 3 weeks or in lower doses weekly during radiation treatment. The high dose and low dose schedules result in a similar total dose of cisplatin being given during the radiation, but it is thought that the weekly schedule results in fewer side effects while maintaining effectiveness and will be used in this trial.

Another approach widely used around the world for patients with head and neck cancer, is to administer the antibody, cetuximab, weekly during radiation. Cetuximab is an antibody which attaches to a receptor on cancer cells. Cetuximab has a very different side effect profile to cisplatin, and has been reported to result in less exacerbation of radiation related side effects. Both cetuximab and cisplatin can reduce the growth of a cancer and increase the effectiveness of radiation. In Australia cetuximab is approved for use in your type of cancer with radiation, though it is only available on the pharmaceutical benefits scheme if you cannot be given cisplatin. All patients being considered for this trial will be deemed to be fit to receive either cisplatin or cetuximab.

Both cisplatin and cetuximab appear to be effective treatments in combination with radiation, but have not been directly compared. It is anticipated that both approaches will achieve high rates of control of your type of cancer. The purpose of this study is to compare the treatment related side effects (both acute and longer term) between the cisplatin and cetuximab regimens. Both treatments would be given with the same dose of radiation therapy over 7 weeks. The results of this trial will help determine the optimal treatment for patients with your type of cancer.

This research is being conducted by the Trans-Tasman Radiation Oncology Group (TROG).

WA Trial Sites

SCGH Radiation Oncology
Ph. (08) 6383 3000

Links
TROG Cancer Research trial 12.01
REGENERON Study

Registered Title  A Phase 2 Study of REGN2810, a Fully Human Monoclonal Antibody to Programmed Death-1 (PD-1), in Patients With Advanced Cutaneous Squamous Cell Carcinoma.

Purpose  To estimate the clinical benefit of REGN2810 monotherapy for patients with metastatic (nodal or distant) cutaneous squamous cell carcinoma (CSCC) (Group 1) or with unresectable locally advanced CSCC (Group 2), as measured by overall response rate (ORR), according to central review.

Lay Summary  N/A

WA Trial Sites

SCGH Medical Oncology
Ph. (08) 6383 3000

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
Lung Cancer and Mesothelioma

Lung Cancer

Br.31 Study

Registered Title
A Phase III Prospective Double Blind Placebo Controlled Randomized Study of Adjuvant MEDI4736 In Completely Resected Non-Small Cell Lung Cancer.

Purpose
The purpose of this study is to find out whether it is better to receive a new drug, MEDI4736, or better to receive no further treatment after surgery (and possibly chemotherapy) for lung cancer.

Lay Summary
N/A

WA Trial Sites

SCGH Medical Oncology
Ph. (08) 6383 3000

Cancer Centre Clinical Trials Unit
Caroline Stone
Clinical Trials Manager
Phone 08 615 26530 Fax 08 615 20954
caroline.stone@health.wa.gov.au

Links
US National Library of Medicine

CheckMate 227 Study

Registered Title  An Open-Label, Randomized Phase 3 Trial of Nivolumab, or Nivolumab Plus Ipilimumab, Versus Platinum Doublet Chemotherapy in Subjects With Chemotherapy-Naïve Stage IV or Recurrent Non-Small Cell Lung Cancer (NSCLC).

Purpose  The purpose of this study is to show that Nivolumab or Nivolumab plus ipilimumab, improves progression free survival and/or overall survival compared with chemotherapy in subjects advanced lung cancer.

Lay Summary  N/A

WA Trial Sites

Tamsyn Whitcher  
Murdoch Oncology Clinical Trials Unit  
Ph. (08) 9428 8539  
oncologytrials.murdoch@sjog.org.au

Caroline Stone  
Cancer Centre Clinical Trials Unit  
Clinical Trials Manager  
Phone 08 615 26530 Fax 08 615 20954  
caroline.stone@health.wa.gov.au

Links  
US National Library of Medicine

NIVORAD Study

Registered Title
NIVORAD - A randomised phase 2 trial of nivolumab and stereotactic ablative body radiotherapy in advanced non-small cell lung cancer, progressing after first or second line chemotherapy.

Purpose
The aim of this study is to determine the activity and safety of treating an asymptomatic, extrathoracic metastasis with a single fraction of SABR, during immunotherapy with nivolumab in advanced NSCLC progressing after 1 or 2 lines of chemotherapy.

Lay Summary
Who is it for?
Adults with advanced non-small-cell lung cancer (NSCLC) progressing after 1 or 2 lines of chemotherapy and with an asymptomatic, extrathoracic metastasis suitable for SABR. Tumour blocks must be available to test for PD-L1 expression.

Study details:
Participants will be randomly allocated in a ratio of 2:1 to either nivolumab 240mg every 2 weeks plus SABR (experimental) or nivolumab 240mg every 2 weeks alone (control). Nivolumab is continued until disease progression or prohibitive toxicity.

Participants will be assessed regularly for treatment response and side effects during the treatment and follow up phase. Clinical assessments will be performed before each cycle of nivolumab (2 weekly) and CT scans at baseline, week 6, 12, 18, 24 then 12 weekly until progression. Anticancer treatments and survival will be reviewed every 12 weeks after progression. This will enable us to determine the activity and safety of each treatment option in patients with an asymptomatic, extrathoracic metastasis.

WA Trial Sites

SCGH Medical Oncology
Ph. (08) 6383 3000

Links
Australian New Zealand Clinical Trials Registry

Acknowledgements: Australian New Zealand Clinical Trials Registry
SAFRON II Trial (TROG Trial 13.01)

Registered Title
A Randomised Phase II Trial of Stereotactic Ablative Fractionated Radiotherapy versus Radiosurgery for Oligometastatic Neoplasia to the lung (SAFRON II).

Purpose
The purpose of this study is to assess toxicity, quality of life, clinical efficacy, cost effectiveness and immunogenicity of single fraction SABR and multi-fraction SABR in patients with limited (≤3) pulmonary metastases.

Lay Summary
Stereotactic Ablative Body Radiotherapy (SABR) is a new form of cancer radiotherapy treatment and there are two SABR techniques emerging in Australia; one which involves a single large treatment session and another which involves multiple smaller sessions.

The main purpose of this study is to examine the side effects of these two SABR techniques relative to each other, as well as to investigate the relative effectiveness and costs associated with each technique. This study will also examine the quality of life of participants who undergo the SABR treatment. By completing this study, we aim to determine which method of delivery is the best to be used in Australia and New Zealand in the future.

Participants will be randomised to receive either: ARM 1: Single Fraction SABR: 28Gy delivered 1 treatment session OR ARM 2: Multi Fraction SABR: 48 Gy delivered in 4 treatment sessions, delivered twice a week over 2 weeks, with each fraction on non-consecutive days.

This research study is expected to recruit 84 participants over a 3 year period.

WA Trial Sites

Department of Radiation Oncology, Sir Charles Gairdner Hospital
Ph. (08) 6383 3202

Links
Trans Tasman Radiation Oncology Group (TROG)
Mesothelioma

BI Mesothelioma Study

Registered Title Double Blind, Randomised, Multicentre, Phase II/III Study of Nintedanib in Combination With Pemetrexed / Cisplatin Followed by Continuing Nintedanib Monotherapy Versus Placebo in Combination With Pemetrexed / Cisplatin Followed by Continuing Placebo Monotherapy for the Treatment of Patients With Unresectable Malignant Pleural Mesothelioma.

Purpose This is a phase II/III confirmatory study designed to evaluate the safety and efficacy of nintedanib (BIBF 1120) in combination + (pemetrexed / cisplatin) followed by nintedanib (BIBF 1120) versus placebo + pemetrexed / cisplatin followed by placebo for the treatment of patients with unresectable malignant pleural mesothelioma.

Lay Summary N/A

WA Trial Sites

SCGH Medical Oncology
Ph. (08) 6383 3000

Mount Hospital Clinical Trials
Ph. (08) 9481 8373

Links US National Library of Medicine

Acknowledgements: US National Library of Medicine
CheckMate 743 Study

Registered Title  A Phase III, Randomized, Open Label Trial of Nivolumab in Combination With Ipilimumab Versus Pemetrexed With Cisplatin or Carboplatin as First Line Therapy in Unresectable Pleural Mesothelioma.

Purpose  The purpose of this study is to test the effectiveness and tolerability of the combination of Nivolumab and Ipilimumab compared to Pemetrexed and Cisplatin or Carboplatin in patients with unresectable pleural mesothelioma.

Lay Summary  N/A

WA Trial Sites

SCGH Medical Oncology
Ph. (08) 6383 3000

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
DREAM Study

Registered Title A phase 2 trial of durvalumab with first line chemotherapy in mesothelioma with a safety run in.

Purpose This study will investigate the effectiveness of durvalumab in combination with standard chemotherapy for mesothelioma.

Lay Summary

Who is it for?

You may be eligible to join this study if you are aged 18 years or above, have had a diagnosis of malignant pleural mesothelioma that is not amenable to curative surgical resection.

Study details

All participants in the study will receive standard first-line chemotherapy for mesothelioma and the new treatment, durvalumab, intravenously on day 1 of each 3 week cycle for a maximum number of 18 cycles. Participants will be followed-up for a minimum of 12 months to determine progression free survival and tumour response rate.

Durvalumab is an antibody (a type of human protein) that works by blocking a body substance called PD-L1. Blocking PD-L1 helps the body’s immune system to attack cancer cells. Research has shown that durvalumab can slow tumour growth and shrink tumours in some people with cancer. We plan to enrol 54 participants in this study from hospitals and clinics throughout Australia. Durvalumab is currently an experimental treatment. This means that it is not yet approved for the treatment of mesothelioma, or any other condition, in Australia, or in other countries.

WA Trial Sites

SCGH Medical Oncology
Ph. (08) 6383 3000

Links

Australian New Zealand Clinical Trials Registry

Acknowledgements: Australian New Zealand Clinical Trials Registry
FGFR FRAME Mesothelioma Study

Registered Title
A two stage, open-label, phase II trial assessing the efficacy of a single oral agent AZD4547 in malignant mesothelioma.

Purpose
This primary purpose of this study is to evaluate the safety and efficacy of AZD4547 for the treatment of malignant mesothelioma which has progressed following first line chemotherapy. You may be eligible to participate in this study if you are aged 25 years or over, and have been diagnosed with mesothelioma which has progressed following first or second line chemotherapy with pemetrexed and cisplatin and/or carboplatin.

Lay Summary
Study details
All participants in this study will receive two oral doses of the study drug, AZD4547 per day for 6 months, with appointments with study staff every 3 weeks throughout this period to monitor side effects and adherence to the medication. Researchers will examine disease progression and survival at 6 months, as well as side effect data from the three-weekly appointments to determine the efficacy and safety of the drug.

Information from this study will then be used to inform researchers on whether continued study of this drug is both worthwhile and safe, in the hope that it may provide a safe and effective second line therapy for mesothelioma in patients whose disease has progressed following first line chemotherapy.

WA Trial Sites

SCGH Medical Oncology
Ph. (08) 6383 3193

Links
Australian New Zealand Clinical Trials Registry

Acknowledgements: Australian New Zealand Clinical Trials Registry
P3BEP Germ Cell Tumour Study

Registered Title

Phase 3 Accelerated BEP Trial:

A randomised phase 3 trial of accelerated versus standard BEP chemotherapy for patients with intermediate and poor-risk metastatic germ cell tumours.

Purpose

The purpose of this study is to determine whether accelerated BEP chemotherapy is more effective than standard BEP chemotherapy in males with intermediate and poor-risk metastatic germ cell tumours.

Lay Summary

Who is it for?

You may be eligible to join this study if you are a male aged 16 years to 45 years old and you have been diagnosed with metastatic germ cell tumour/s in the testes, retro-peritoneum or mediastinum.

Study details

Participants in this study will be randomly (by chance) allocated to one of two groups. Participants in one group will receive the current gold standard treatment for germ cell tumours, which is a chemotherapy combination called BEP (bleomycin, etoposide and cisplatin) administered on a 3 weekly cycle. BEP is given with a drug called pegfilgrastim which encourages white blood cell production and prevents blood cell complications of chemotherapy. Participants in the other group will receive the same dose of BEP but on a 2 weekly schedule. This is called ‘accelerated BEP’.

WA Trial Sites

Cancer Centre Clinical Trials Unit
Caroline Stone
Clinical Trials Manager
Phone 08 615 26530 Fax 08 615 20954
caroline.stone@health.wa.gov.au

Links

Australian New Zealand Clinical Trials Registry

Acknowledgements: Australian New Zealand Clinical Trials Registry
Prostate

EMBARK Study

Registered Title  A Phase 3, Randomized, Efficacy and Safety Study of Enzalutamide Plus Leuprolide, Enzalutamide Monotherapy, and Placebo Plus Leuprolide in Men With High-Risk Nonmetastatic Prostate Cancer Progressing After Definitive Therapy.

Purpose  The purpose of this study is to assess enzalutamide plus leuprolide in patients with high-risk nonmetastatic prostate cancer progressing after radical prostatectomy or radiotherapy or both.

Lay Summary  N/A

WA Trial Sites

Cancer Centre Clinical Trials Unit
Caroline Stone
Clinical Trials Manager
Phone 08 615 26530 Fax 08 615 20954
caroline.stone@health.wa.gov.au

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
ENZARAD Trial

Registered Title  Randomised phase 3 trial of enzalutamide in androgen deprivation therapy with radiation therapy for high risk, clinically localised, prostate cancer.

Purpose  The purpose of this study is to determine the effectiveness of enzalutamide as part of adjuvant androgen deprivation therapy (ADT) with a luteinizing hormone releasing hormone analogue (LHRHA) in men having radiation therapy for localised prostate cancer at high risk of recurrence.

Lay Summary  N/A

WA Trial Sites  GenesisCare

For more information about trials with GenesisCare in Western Australia, phone 1300 977 062 and ask to speak to one of the trials coordinators, or speak to your GenesisCare radiation oncologist.

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
**Metastatic Hormone Sensitive Prostate Cancer Study**

**Registered Title**  
A Multinational, Phase 3, Randomized, Double-blind, Placebo-controlled Efficacy and Safety Study of Enzalutamide Plus Androgen Deprivation Therapy (ADT) Versus Placebo Plus ADT in Patients with Metastatic Hormone Sensitive Prostate Cancer (mHSPC).

**Purpose**  
A study for patients with metastatic hormone sensitive prostate cancer (mHSPC) (first or second line). The purpose of the study is to see if a medicine called enzalutamide when added androgen deprivation therapy (which is the standard therapy to treat mHSPC to lower testosterone) will delay disease progression.

**Lay Summary**  
N/A

**WA Trial Sites**

Mount Hospital Clinical Trials  
Ph. (08) 9481 8373

**Links**  

Acknowledgements: US National Library of Medicine
Quality of Life, Survivorship and Lifestyle

Care After Lymphoma

Registered Title  Care After Lymphoma (CALy) Trial: A randomised controlled trial testing the effect of a pilot nurse-led lymphoma survivorship clinic with lymphoma survivors to decrease the number of unmet informational needs to reduce anxiety, stress and to increase self-empowerment.

Purpose  This project aims to develop and test a nurse-led model of survivorship care for lymphoma survivors.

Lay Summary  Participants will be randomly allocated to one of two groups. Participants in one group will continue to receive usual follow-up care with their haematologist. Participants in the other group will take part in an evidenced-based survivorship clinic that will provide tailored care to patients who have completed active treatment. The intervention will involve three 1 hour face-to-face structured interviews that will occur over a 6 month period. These will involve discussion and delivery of a survivorship care plan, treatment summary and resource pack. Participants in both groups will be asked to complete a number of questionnaires at baseline, 3 months and 6 months in order to evaluate unmet informational and practical needs, depression, anxiety, stress, coping and self-empowerment. The findings from this study will make a significant contribution to the planning and delivery of survivorship care.

WA Trial Sites

Haematology Care Centre
Sir Charles Gairdner Hospital
Ph. (08) 6383 3207
Fax (08) 9346 4432
Email: louise.hay@health.wa.gov.au

Links  Australian New Zealand Clinical Trials Registry

Acknowledgements: Australian New Zealand Clinical Trials Registry
Exercise medicine for all cancer survivors: Implementation and evaluation of a national intervention program

Title
Exercise medicine for all cancer survivors: Implementation and evaluation of a national intervention program.

Purpose
The purpose of this study is to implement and assess the effectiveness (including cost effectiveness) of an exercise medicine program for cancer survivors.

Lay Summary
Exercise has been established to be safe and result in improved physical function and quality of life for cancer patients. The majority of cancer survivors do not participate in enough exercise or are completely inactive. More information is required regarding the impact of exercise on survivors of a range of various cancer diagnoses.

WA Trial Sites
Edith Cowan University Exercise Medicine Research Institute.
Patients who may be eligible for any of these projects can contact our team for on 6304 2329 or at emri@ecu.edu.au.

Links
[ECU Exercise Medicine Research Institute](http://example.com)
Exercise program for patients with malignant pleural disease

Title  Exercise program for patients with malignant pleural disease.

Purpose  Participation in this study is anticipated to improve nutritional status, body composition, and physical functioning over time. Site available is Sir Charles Gairdner Hospital.

Lay Summary  Following a diagnosis of mesothelioma there can be declines in health and wellbeing. Many people experience weight loss, poor appetite, tiredness, shortness of breath, and pain. No research has examined how nutritional status (i.e., how well your diet is meeting your nutritional needs), physical functioning (e.g., ability to do tasks such as walking and lifting), and body composition (i.e., how much fat and muscle you have) changes over time for patients with mesothelioma.

WA Trial Sites  Edith Cowan University Exercise Medicine Research Institute.

Patients who may be eligible for any of these projects can contact our team for on 6304 2329 or at emri@ecu.edu.au.

Links  ECU Exercise Medicine Research Institute
Exercise as medicine in the management of pancreatic cancer

Title Exercise as medicine in the management of pancreatic cancer.

Purpose This project will examine the potential role of a targeted exercise program in enhancing the ability to tolerate and recover from treatments and optimise physical, mental and social quality of life in people with pancreatic cancer.

Lay Summary Given the poor prognosis for people diagnosed with pancreatic cancer, maximising quality of life is vitally important. As such, therapies that enhance the ability to tolerate intensive treatments, reduce the loss of physical functioning and optimise quality of life are critical but there are no such therapies currently available. Exercise may represent such a therapy, as research in patients with prostate and breast cancer has established that appropriate exercise counteracts many adverse side effects of cancer treatments (e.g. fatigue, psychological distress, functional decline) while improving quality of life.

WA Trial Sites Edith Cowan University Exercise Medicine Research Institute.

Patients who may be eligible for any of these projects can contact our team for on 6304 2329 or at emri@ecu.edu.au.

Links ECU Exercise Medicine Research Institute
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<th><strong>Finding My Way</strong></th>
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<tr>
<td><strong>Title</strong></td>
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<td><strong>Lay Summary</strong></td>
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<tr>
<td><strong>WA Trial Sites</strong></td>
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<tr>
<td><strong>Links</strong></td>
</tr>
</tbody>
</table>
Improving sexual health in men with prostate cancer

Title
Improving sexual health in men with prostate cancer: randomised controlled trial of exercise and psychosexual therapies.

Purpose
This project examines whether exercise aids in the management of sexual dysfunction and explores if an integrated treatment model incorporating pharmacological, exercise and psychosexual therapies maximises improvement in sexual health.

Lay Summary
Sexual dysfunction is one of the most common and distressing side effects of prostate cancer. Despite being a critical survivorship care issue, there is a clear gap in knowledge surrounding the optimal treatment of sexual dysfunction in men with prostate cancer.

- Inclusion criteria: Concerned by your sexual wellbeing; prior/current treatment for prostate cancer including prostatectomy, radiotherapy or ADT.
- Exclusion criteria: Non-nerve sparing prostatectomy; > 6 months since prostatectomy or completion of radiotherapy or ADT; incontinence defined as requiring the use of > 1 pad in a 24-hour period.

WA Trial Sites
Edith Cowan University Exercise Medicine Research Institute.
Sites available: Joondalup, Mt Lawley, Crawley, Fremantle and Murdoch.
Patients who may be eligible for any of these projects can contact our team for on 6304 2329 or at emri@ecu.edu.au

Links
ECU Exercise Medicine Research Institute
INTense Exercise for Survival among Men with Metastatic Castrate-Resistant Prostate Cancer (INTERVAL – MCRPC) (GAP4)

Title
INTense Exercise for Survival among Men with Metastatic Castrate-Resistant Prostate Cancer (INTERVAL – MCRPC) (GAP4).

Purpose
The primary objective of this study is to determine if high intensity aerobic and resistance training plus psychosocial support increases overall survival compared to psychosocial support alone in prostate cancer patients. The term psychosocial relates to the interrelation of psychological and social thoughts and behaviours, thus support of this nature will be provided to all participants.

Lay Summary
Exercise has been established as a safe and effective activity leading to improved physical function and quality of life in men with prostate cancer. However, little information exists regarding whether exercise can increase overall survival and reduce disease progression, skeletal-related events, and pain in patients with metastatic castrate-resistant prostate cancer.

WA Trial Sites
Edith Cowan University Exercise Medicine Research Institute.

Patients who may be eligible for any of these projects can contact our team for on 6304 2329 or at emri@ecu.edu.au.

Links
ECU Exercise Medicine Research Institute
Mechanical modulation of bone metastases in advanced breast cancer patients: Can targeted exercise suppress osteolytic tumour progression?

**Title**
Mechanical modulation of bone metastases in advanced breast cancer patients: Can targeted exercise suppress osteolytic tumour progression?

**Purpose**
We aim to provide a safe and supervised exercise program which also targets bones with secondary tumours to slow tumour growth, reduce bone pain, and increase survival.

**Lay Summary**
Exciting new evidence suggests that there is an additional benefit to cancer patients if exercise programs directly target regions where bone was invaded by cancer. In particular, it seems that exercising bones with tumours has the ability to slow down tumour growth while also preventing bone loss. This has the potential to increase the survival of advanced breast cancer patients, and has the potential to preserve bone and muscle which will lead to increased physical function, quality of life and reduced bone pain.

**WA Trial Sites**
Edith Cowan University Exercise Medicine Research Institute.

Patients who may be eligible for any of these projects can contact our team for on 6304 2329 or at emri@ecu.edu.au.

**Links**
ECU Exercise Medicine Research Institute
Mechanical modulation of bone metastases in advanced prostate cancer patients

**Title**

**Purpose**
We aim to provide a safe and supervised exercise program which also targets bones with secondary tumours to slow tumour growth, reduce bone pain, and increase survival.

**Lay Summary**
Exciting new evidence suggests that there is an additional benefit to cancer patients if exercise programs directly target regions where bone was invaded by cancer. In particular, it seems that exercising bones with tumours has the ability to slow down tumour growth while also preventing bone loss. This has the potential to increase the survival of advanced prostate cancer patients, and has the potential to preserve bone and muscle which will lead to increased physical function, quality of life and reduced bone pain.

**WA Trial Sites**
Edith Cowan University Exercise Medicine Research Institute.

Patients who may be eligible for any of these projects can contact our team for on 6304 2329 or at emri@ecu.edu.au.

**Links**
[ECU Exercise Medicine Research Institute](ECU Exercise Medicine Research Institute)
Program of Exercise Medicine for Men on Prostate Cancer Active Surveillance

Title
Preliminary Efficacy of Implementing a Program of Exercise Medicine for Men on Prostate Cancer Active Surveillance - A Pilot Study.

Purpose
Our aim is to determine the feasibility and efficacy of implementing a program of exercise medicine specifically prescribed to ameliorate the primary physical and mental health problems faced by men on prostate cancer active surveillance and explore potential mechanisms underlying the influence of physical exercise on markers of disease progression.

Lay Summary
Exercise has been established to be safe and result in improved physical function and quality of life for cancer patients. Our team and others have consistently demonstrated that exercise improves physical and mental health in men with prostate cancer during and following completion of therapeutic interventions. More specifically, resistance and aerobic exercise have been shown to enhance the musculoskeletal system, improve cardiorespiratory capacity, prevent functional decline, improve sexual health, body composition, endocrine and immune function as well as overall quality of life. A recent and very exciting discovery suggests that, in some cases, exercise may actually suppress tumour progression. However, all of the exercise clinical trials to date have included patients during or following surgery, radiation or hormone treatment. There are no established recommendations for improving active surveillance adherence, slowing disease progression, delaying time to active curative treatment, or reducing active surveillance-specific anxiety and distress.

WA Trial Sites
Edith Cowan University Exercise Medicine Research Institute.
Patients who may be eligible for any of these projects can contact our team for on 6304 2329 or at emri@ecu.edu.au.

Links
ECU Exercise Medicine Research Institute
Sexual Healing

Registered Title
A Randomised, Controlled Trial on the Effect of Pre-Operative Sexual Counselling on Sexuality and Quality of Life after Risk-Reducing Salpingo-oophrectomy.

Purpose
This study will determine the effect of pre-operative sexual counselling on sexuality and quality of life after risk reducing salpingo-oophorectomy (RRSO) in women at high risk of ovarian cancer.

Lay Summary
Who is it for?
You may be eligible to join this study if you are aged 18 years or above, at high risk of ovarian cancer and have decided to undergo risk-reducing salpingo-oophorectomy.

Study details
Participants in this study are randomly allocated (by chance) to one of two groups. Participants in one group will receive a single pre-operative counselling session with a sexologist to discuss the potential effects of surgery on sexual function and physical changes, potential changes to intimacy, loss of sexual self-esteem related to body image changes, menopausal symptoms and confidence, changes to sexual response such as reduced arousal, loss of libido, difficulty reaching orgasm, menopausal symptoms related to treatment including hot flushes/night sweats, disturbed sleep, poor memory and weight gain, all of which may impact on one's sexual self esteem, sexual functioning and general wellbeing (quality of life).

While participants in the other group will receive routine care which is the initial consultation with your gynaecologic oncology specialist who may or may not discuss such issues with you. Participants will be followed-up for up to 12 months post-surgery to determine the effect on sexual function, the prevalence and severity of sexual difficulties after RRSO, and any other factors that significantly affect sexual function and quality of life. Serum testosterone levels will also be tested to determine whether there is a correlation with sexual function after RRSO.

WA Trial Sites
St John of God
Ph. (08) 6464 9204

Links
Australian New Zealand Clinical Trials Registry

Acknowledgements: Australian and New Zealand Clinical Trials Registry
The effect of either a pre- or post-exercise intervention on patient outcomes for prostate cancer patients undergoing prostatectomy

| Title | The effect of either a pre- or post-exercise intervention on patient outcomes for prostate cancer patients undergoing prostatectomy. |
| Purpose | We are investigating the effects of pre or post-surgical exercise intervention in cancer patients undergoing prostatectomy. This study will evaluate an exercise medicine intervention undertaken pre-surgery aimed at enhancing pre-surgical physical function, quality of life and improved post-surgical recovery. Study outcomes will provide supportive evidence for the role of pre-surgical exercise in the management of prostate cancer. |
| Lay Summary | N/A |
| WA Trial Sites | Edith Cowan University Exercise Medicine Research Institute. Patients who may be eligible for any of these projects can contact our team for on 6304 2329 or at emri@ecu.edu.au. |
| Links | ECU Exercise Medicine Research Institute |
Skin Cancer

CheckMate 401 (CA209-401) Study

Registered Title  Clinical Trial of Nivolumab (BMS-936558) Combined With Ipilimumab Followed by Nivolumab Monotherapy as First-Line Therapy of Subjects With Histologically Confirmed Stage III (Unresectable) or Stage IV Melanoma CheckMate 401: CHECKpoint Pathway and nivoluMAb Clinical Trial Evaluation 401.

Purpose  The purpose of this study is to determine the effects of combination treatment of Nivolumab with Ipilimumab followed by Nivolumab monotherapy in patients with previously untreated advanced Melanoma.

Lay Summary  N/A

WA Trial Sites

Tamsyn Whitcher
Murdoch Oncology Clinical Trials Unit
Ph. (08) 9428 8539
oncologytrials.murdoch@sjog.org.au

SCGH Medical Oncology
Ph. (08) 6383 3000

Links  US National Library of Medicine

MASTERKEY 265 Study

Registered Title  A Phase 1b/3, Multicenter, Trial of Talimogene Laherparepvec in Combination With Pembrolizumab (MK-3475) for Treatment of Unresectable Stage IIIB to IVM1c Melanoma (MASTERKEY-265).

Purpose  Phase 1b Subjects will be treated with talimogene laherparepvec until all injectable tumors have disappeared, disease progression per modified Immune-Related Response Criteria (irRC), or intolerance of study treatment, up to a maximum of 24 months of study treatment. Subjects will be treated with MK-3475 (pembrolizumab) until complete response (CR) disease progression per irRC, or intolerance of study treatment, up to a maximum of 24 months of study treatment. In Phase 3, Subjects will be treated with talimogene laherparepvec plus pembrolizumab (arm 1) or placebo plus pembrolizumab (arm 2) until 24 months from the date of the first dose of pembrolizumab or end of treatment due to disappearance of injectable lesions, complete response, disease progression per irRC-RECIST or intolerance of study treatment.

Lay Summary  N/A

WA Trial Sites

Cancer Centre Clinical Trials Unit
Caroline Stone
Clinical Trials Manager
Phone 08 615 26530 Fax 08 615 20954
caroline.stone@health.wa.gov.au

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
TACTI-mel Study

**Registered Title**  
A Multicentre, Open Label, Dose Escalation, Phase 1 Study in Patients With Unresectable or Metastatic Melanoma Receiving IMP321 (LAG-3Ig Fusion Protein) as an Adjunctive Therapy to Anti-PD-1 Therapy With Pembrolizumab.

**Purpose**  
The purpose of this study is to determine the safety, tolerability and recommended phase 2 dose of a new drug, known as IMP321, in combination with pembrolizumab when given to patients with unresectable or metastatic melanoma.

**Lay Summary**  
N/A

**WA Trial Sites**

Cancer Centre Clinical Trials Unit  
Caroline Stone  
Clinical Trials Manager  
Phone 08 615 26530 Fax 08 615 20954  
caroline.stone@health.wa.gov.au

**Links**  

Acknowledgements: US National Library of Medicine
## ACTICCA-1 Gallbladder Carcinoma Study

<table>
<thead>
<tr>
<th>Registered Title</th>
<th>Adjuvant Chemotherapy With Gemcitabine and Cisplatin Compared to Observation After Curative Intent Resection of Cholangiocarcinoma and Muscle Invasive Gall Bladder Carcinoma (ACTICCA-1 Trial).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
<td>This is a multicentre, prospective, randomized, controlled phase III trial designed to assess the clinical performance of gemcitabine with cisplatin and observation vs. observation alone in patients after curative intent resection of cholangiocarcinoma and muscle invasive gall bladder carcinoma.</td>
</tr>
<tr>
<td>Lay Summary</td>
<td>N/A</td>
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</tbody>
</table>
| WA Trial Sites   | SCGH Medical Oncology  
Ph. (08) 6383 3000  

Acknowledgements: US National Library of Medicine
ALT GIST Study

Registered Title  A Randomised Phase II Trial of Imatinib Alternating With Regorafenib Compared to Imatinib Alone for the First Line Treatment of Advanced Gastrointestinal Stromal Tumour (GIST).

Purpose  An open label randomised trial for adults with histologically confirmed measurable metastatic GIST who have received no other treatment for metastatic disease. The study aims to determine if an alternating regimen of imatinib and regorafenib has sufficient activity and safety in comparison to imatinib alone to warrant further evaluation as a first line treatment for metastatic GIST.

Lay Summary  N/A

WA Trial Sites

SCGH Medical Oncology
Ph. (08) 6383 3000

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
### A Phase 2 Metastatic Pancreatic Cancer Trial

#### Registered Title
A Randomized, Open-label Phase 2 Study of Nanoliposomal Irinotecan (Nal-IRI)-Containing Regimens Versus Nab-Paclitaxel Plus Gemcitabine in Patients With Previously Untreated, Metastatic Pancreatic Adenocarcinoma.

#### Purpose
This is an open-label, phase 2 comparative study to assess the safety, tolerability, and efficacy of nal-IRI in combination with other anticancer therapies, compared to nab-paclitaxel + gemcitabine, in patients with advanced pancreatic adenocarcinoma who have not received prior chemotherapy.

#### Lay Summary
N/A

#### WA Trial Sites

![St John of God Healthcare](image)

St John of God  
Ph. (08) 6464 9204

#### Links
[US National Library of Medicine](#)

Acknowledgements: US National Library of Medicine
BRIGHTER Study

Registered Title  A Phase III Randomized, Double-Blind, Placebo-Controlled Clinical Trial of BBI608 plus weekly Paclitaxel vs. Placebo plus Weekly Paclitaxel in Adult Patients with Advanced, Previously Treated Gastric and Gastro-Esophageal Junction Adenocarcinoma.

Purpose  The purpose of this study is to find out whether it is better to receive a new drug, BBI608, in addition to paclitaxel chemotherapy or better to receive paclitaxel chemotherapy alone as second line treatment for gastric and gastroesophageal junction cancer after prior first line platinum and fluoropyrimidine based chemotherapy.

Lay Summary  N/A

WA Trial Sites

Cancer Centre Clinical Trials Unit
Caroline Stone
Clinical Trials Manager
Phone 08 615 26530 Fax 08 615 20954
caroline.stone@health.wa.gov.au

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
**CONTROL NETs Study**

<table>
<thead>
<tr>
<th>Registered Title</th>
<th>CONTROL NETs: Capecitabine ON Temozolomide Radionuclide therapy Octreotide Lutetium-177 NeuroEndocrine Tumours Study.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
<td>The CONTROL NETS study aims to determine the activity of capecitabine + temozolomide (CAPTEM)/peptide receptor radionuclide therapy (PRRT), alone and in combination, in both pancreatic neuroendocrine tumours (pNETS) and mid-gut neuroendocrine tumours (mNETS) patients.</td>
</tr>
<tr>
<td>Lay Summary</td>
<td>N/A</td>
</tr>
</tbody>
</table>
| WA Trial Sites   | Cancer Centre Clinical Trials Unit  
|                  | Caroline Stone  
|                  | Clinical Trials Manager  
|                  | Phone 08 615 26530 Fax 08 615 20954  
|                  | caroline.stone@health.wa.gov.au                                                                                                                                     |
| Links            | [Australian New Zealand Clinical Trials Registry](https://www.anzctr.org.au)                                                                                         |

Acknowledgements: Australian New Zealand Clinical Trials Registry
INTEGRATE II Gastro-Oesophageal Cancer Study

Registered Title A Randomised Phase III Double-Blind Placebo-Controlled Study of Regorafenib in Refractory Advanced Gastro-Oesophageal Cancer (AGOC).

Purpose Advanced Gastro-oesophageal Carcinoma (AGOC) has a poor prognosis, and there is no established standard treatment following failure of first and second line chemotherapy. Regorafenib (BAY 73-4506) is an investigational oral multi-targeted tyrosine kinase inhibitor (TKI) which targets angiogenic (VEGF, TIE-2), stromal (PDGF-β), and oncogenic (RAF, RET and KIT) receptor tyrosine kinases, and has shown activity in other solid tumours. Regorafenib was shown to prolong PFS across all regions/subgroups in INTEGRATE I. The general aim of this study is to determine if regorafenib improves overall survival in refractory AGOC.

Lay Summary N/A

WA Trial Sites

St John of God
Ph. (08) 6464 9204

SCGH Medical Oncology
Ph. (08) 6383 3000

Links US National Library of Medicine

Acknowledgements: US National Library of Medicine
**Javelin Gastric 100 Study**

**Registered Title**  
A Phase III Open-label, Multicenter Trial of Maintenance Therapy With Avelumab (MSB0010718C) Versus Continuation of First-line Chemotherapy in Subjects With Unresectable, Locally Advanced or Metastatic, Adenocarcinoma of the Stomach, or of the Gastro-esophageal Junction.

**Purpose**  
The purpose of this study is to demonstrate superiority of treatment with avelumab versus continuation of first-line chemotherapy.

**Lay Summary**  
N/A

**WA Trial Sites**

Cancer Centre Clinical Trials Unit  
Caroline Stone  
Clinical Trials Manager  
Phone 08 615 26530 Fax 08 615 20954  
caroline.stone@health.wa.gov.au

**Links**  

Acknowledgements: US National Library of Medicine
### KEYNOTE-181 Oesophageal Cancer Study

**Registered Title**  

**Purpose**  
In this study, participants with advanced or metastatic adenocarcinoma or squamous cell carcinoma of the esophagus or Siewert type I adenocarcinoma of the esophagogastric junction (EGJ) that has progressed after first-line standard therapy will be randomized to receive either single agent pembrolizumab or the Investigator's choice of standard therapy with paclitaxel, docetaxel, or irinotecan. The primary study hypothesis is that treatment with pembrolizumab will prolong progression-free survival (PFS) and/or overall survival (OS) as compared to treatment with standard therapy.

**Lay Summary**  
N/A

**WA Trial Sites**

| St John of God | Ph. (08) 6464 9204 |

**Links**  
[US National Library of Medicine](https://ClinicalTrials.gov/show/NCT03027873)

Acknowledgements: US National Library of Medicine
MSD Gastric 062 Study

Registered Title
A Randomized, Active-Controlled, Partially Blinded, Biomarker Select, Phase III Clinical Trial of Pembrolizumab as Monotherapy and in Combination With Cisplatin+5-Fluorouracil Versus Placebo+Cisplatin+5-Fluorouracil as First-Line Treatment in Subjects With Advanced Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma.

Purpose
This is a study of pembrolizumab (MK-3475) as first-line treatment for participants with advanced gastric or gastroesophageal junction (GEJ) adenocarcinoma. Participants will be randomly assigned to one of the 3 treatment arms of the study: pembrolizumab as monotherapy, or pembrolizumab + cisplatin + 5-fluorouracil (5-FU) or capecitabine, or placebo + cisplatin + 5-FU or capecitabine. The primary hypothesis is that pembrolizumab provides a clinically meaningful progression free and/or overall survival.

Lay Summary
N/A

WA Trial Sites
SCGH Medical Oncology
Ph. (08) 6383 3000

Links
US National Library of Medicine

Acknowledgements: US National Library of Medicine
NABNEC Gastrointestinal Neuroendocrine Carcinomas Study

Registered Title
A Randomised Phase II Study Of nab-paclitaxel In Combination With Carboplatin As First Line Treatment Of Gastrointestinal Neuroendocrine Carcinomas.

Purpose
The primary purpose of this trial is to evaluate the safety and efficacy of carboplatin plus nab-paclitaxel in comparison with carboplatin plus etoposide chemotherapy for the treatment of gastrointestinal neuroendocrine carcinomas (NECs).

Lay Summary
Who is it for?
You may be eligible to enrol in this trial if you are aged 18 or over, and have been diagnosed with advanced and/or metastatic, unresectable gastrointestinal neuroendocrine carcinoma (NEC).

Study details
All participants enrolled in this trial will be randomly allocated (by chance) to receive either carboplatin plus nab-paclitaxel or carboplatin plus etoposide. Participants receiving carboplatin plus nab-paclitaxel will be required to visit the study site once per week, for weekly administration of nab-paclitaxel plus administration of carboplatin once every three weeks. Participants receiving carboplatin plus etoposide will be required to visit the study site for three consecutive days every three weeks for administration of etoposide plus administration of carboplatin once every three weeks. Treatment will continue for all participants until disease progression or until side effects become unmanageable. All participants will be reviewed for side effects, outcomes of survival and cancer progression. Blood and tissue samples will also be taken, as well as specialised scans, to identify markers of prognosis and response. It is hoped that the findings of this trial will identify which treatment is the most promising, for further investigation to be undertaken to guide best practice.

WA Trial Sites

St John of God
Ph. (08) 6464 9204

Cancer Centre Clinical Trials Unit
Caroline Stone
Clinical Trials Manager
Phone 08 615 26530 Fax 08 615 20954
caroline.stone@health.wa.gov.au

Links
Australian New Zealand Clinical Trials Registry

Acknowledgements: Australian New Zealand Clinical Trials Registry
PHOCUS Advanced Hepatocellular Carcinoma Study

Registered Title

Purpose
This is a randomized Phase 3 study to determine whether treatment with vaccinia virus based immunotherapy (Pexa-Vec) followed by sorafenib increases survival compared to treatment with sorafenib in patients with advanced hepatocellular carcinoma who have not received prior systemic therapy.

Lay Summary
N/A

WA Trial Sites
St John of God
Ph. (08) 6464 9204

Links
US National Library of Medicine

Acknowledgements: US National Library of Medicine
SIRCCA Study

Registered Title  Prospective, Multicenter, Randomized, Controlled Study Evaluating SIR-Spheres Y-90 Resin Microspheres Preceding Cisplatin-gemcitabine (CIS-GEM) Chemotherapy Versus CIS-GEM Chemotherapy Alone as First-line Treatment of Patients With Unresectable Intrahepatic Cholangiocarcinoma.

Purpose  The study will evaluate the benefit of applying Selective Internal Radiation Therapy (SIRT) using SIR-Spheres Y-90 resin microspheres prior to receiving systemic chemotherapy treatment (cisplatin-gemcitabine, or CIS-GEM) in patients with unresectable intrahepatic cholangiocarcinoma. Half of the patients will be randomized to CIS-GEM chemotherapy plus SIRT, and half of the patients will be randomized to CIS-GEM alone.

Lay Summary  N/A

WA Trial Sites

SCGH Medical Oncology
Ph. (08) 6383 3000

Links  US National Library of Medicine

Acknowledgements: US National Library of Medicine
Registered Title A randomised phase II/III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for resectable gastric cancer.

Purpose The primary objective is to investigate whether the addition of chemoradiotherapy to chemotherapy is superior to chemotherapy alone in the neoadjuvant setting by improving pathological complete response (pCR) rates in the first instance, and subsequently overall survival, in patients undergoing adequate surgery (D1 dissection) for resectable gastric cancer.

Lay Summary The optimal management of patients with resectable gastric cancer continues to evolve. Chemotherapy regimes are better, radiation techniques have improved and there is an increasing interest in the use of chemoradiotherapy prior to surgery for gastric cancer. The important question addressed in this trial is whether chemoradiation is better than chemotherapy alone in the treatment of resectable gastric cancer.

WA Trial Sites

SCGH Radiation Oncology
Ph. (08) 6383 3000

Links Trans-Tasman Radiation Oncology Group
Australian New Zealand Clinical Trials Registry