CLINICAL TRIALS

30 JUNE 2023

ANZ GOG

Improving life for women through cancer research

TRIALS RECRUITING as at 30 June 2023

ENDOMETRIAL CANCER

Study	**ENDO-3**
Title	A Phase III Randomised Clinical Trial Comparing Sentinel Node Biopsy with No Retroperitoneal Node Dissection in Apparent Early-Stage Endometrial Cancer
Principal Investigator	Prof Andreas Obermair
Collaborations	Initiated in Australia by the University of Queensland (Queensland Centre of Gynaecological Cancer) in collaboration with ANZGOG and GCIG.
Funding	Soft funding only acquired to date for project management. Grant opportunities sort and applied for is ongoing
Study Milestones	Planned Sample Size: 760 Planned Number of Sites: Open to all sites (nationally and internationally) pending accreditation, ethics and governance requirements are met Actual: 83 participants | 5 sites
Contact	**endo3trial@health.qld.gov.au**
Summary  Prof Andreas Obermair Principal Investigator	Endometrial cancer (EC) is the most common gynaecological cancer. Current treatment of EC typically includes removal of the uterus and to determine the extent of the disease (removal of fallopian tubes, ovaries & if required a lymph node dissection (surgical staging)). While lymph node dissection may be valuable to guide the need for adjuvant treatment (chemo or radiotherapy) after surgery, it has been a topic of controversy for the last 30 years. In some patients it causes morbidity, specifically lymphoedema. This recently has been replaced with sentinel node biopsy (SNB). It requires an injection of a dye into the cervix with specific equipment & surgical dissection of the lymph node in which the dye first becomes visible. Despite this promising proposition & similar to a lymph node dissection, the value to patients, cost effectiveness & potential harms (e.g. lymphedema) of SNB compared to no-node dissection in EC has never been established. The aim of the study is to determine the value of SNB for patients, the healthcare system and exclude detriment to patients using a randomised approach 1:1.

TRIALS RECRUITING as at 30 June 2023

ENDOMETRIAL CANCER

Study	**ADELE**
Title	Adjuvant Tislelizumab plus chemotherapy after post-operative pelvic chemoradiation in high risk endometrial cancer.
Principal Investigator	Prof Linda Mileshkin Dr Yeh Chen Lee (Co-Chair)
Collaborations	Initiated in Australia by ANZGOG in collaboration with the NHMRC CTC
Funding	Medical Research Future Fund (MRFF) - Clinical Trials Activity (Rare Cancers, Rare Diseases and Unmet Need) – Reproductive Cancers Grant BeiGene
Study Milestones	Planned Sample Size: 135 Planned Number of Sites: 23 Actual: 17 patients randomised and 11 active sites.
Contact	**ADELE.study@sydney.edu.au**
Summary	 Prof Linda Mileshkin Principal Investigator This clinical trial seeks to improve outcomes for women with high-risk endometrial cancer, who have a significant risk of relapse after standard post-operative treatment with chemotherapy and radiotherapy. The trial will find out if relapse rates can be lowered by adding immunotherapy to current standard therapy. Women will be randomly assigned to receive the new treatment combination or existing standard treatment, then followed up to see if outcomes are improved and what side-effects occur.

TRIALS RECRUITING as at 30 June 2023

OVARIANCANCER

Study	**HyNOVA**
Title	A randomised study comparing Hyperthermic and Normothermic intraperitoneal chemotherapy following interval cytoreductive surgery for stage III epithelial ovarian, fallopian tube and primary peritoneal cancer.
Principal Investigator	Assoc Prof Rhonda Farrell
Collaborations	Initiated in Australia by ANZGOG in collaboration with the NHMRC CTC
Funding	Medical Research Future Fund (MRFF) - Clinical Trials Activity (Rare Cancers, Rare Diseases and Unmet Need) – Reproductive Cancers Grant
Study Milestones	Planned Sample Size: 80 Planned Number of Sies: 4 Actual: 17 patients randomised I 3 sites
Contact	**HyNOVA.study@sydney.edu.au**
Summary  Assoc Prof Rhonda Farrell Principal Investigator	HyNOVA is a clinical trial comparing the effect of heated chemotherapy given into the abdominal cavity at a temperature of 42°C (HIPEC) to that given at body temperature of 37°C (NIPEC) at the time of surgery to women with advanced cancer of the ovary, fallopian tube or peritoneum. A recent study showed better survival in this group after treatment with HIPEC compared with no HIPEC. However, oncologists remain undecided about the potential benefit and harm of applying heat to the chemotherapy.

TRIALS RECRUITING as at 30 June 2023

OVARIAN/ENDOMETRIAL CANCER

Study	**PARAGON-II**
Title	Phase II basket study of an ARomatase inhibitor plus PI3KCA inhibitor or CDK4/6 inhibitor in women with hormone receptor positive recurrent/metastatic Gynaecological Neoplasms.
Principal Investigator	Assoc Prof Chee Khoon Lee Prof Michael Friedlander AM (Co-Chair)
Collaborations	Initiated in Australia by ANZGOG in collaboration with the NHMRC CTC
Funding	Medical Research Future Fund (MRFF) - Clinical Trials Activity (Rare Cancers, Rare Diseases and Unmet Need) – Reproductive Cancers Grant
Study Milestones	Planned Sample Size: 182 Planned Number of Sites: 16 Actual: 65 participants | 13 sites
Contact	**PARAGON2.study@sydney.edu.au**
Summary  Assoc Prof Chee Khoon Lee Principal Investigator	PARAGON-II is a trial for women with gynaecological cancers whose tumours are potentially treatable with hormonal treatment. These patients must have cancers that have recurred or metastasised. For patients whose cancers have a genetic mutation called PIK3CA, they will be treated with letrozole hormonal treatment and alpelisib that targets PI3KCA. For those without PIK3CA mutation, these patients will be treated with letrozole and ribociclib, another new oral targeted treatment.

TRIALS RECRUITING as at 30 June 2023

OVARIAN/UTERINE CANCER

Study	**EPOCH**
Title	A Phase II open labelled study investigating the use of single agent eribulin and eribulin in combination with pembrolizumab in relapsed tubo-ovarian or uterine carcinosarcoma.
Principal Investigator	Prof Clare Scott AM
Collaborations	Initiated in Australia by ANZGOG in collaboration with Imperial College London and Princess Margaret Cancer Centre
Funding	ANZGOG – OASIS Initiative, Baker Foundation
Study Milestones	Planned Sample Size: 14 (ANZ) | 30 (Globally) Planned Number of Sites: 4 ANZ | 6 (Globally) Accrual: 0 participants | 1 site
Contact	john.andrews@anzgog.org.au
Summary  Prof Clare Scott AM Principal Investigator	EPOCH is an international clinical trial, which aims to improve outcomes in women with tubo-ovarian or uterine carcinosarcoma. The underlying study rationale is based on robust preclinical evidence that demonstrated that eribulin, a microtubule inhibitor, can reprogram the tumour microenvironment, reversing epithelial mesenchymal transition (EMT) in these mesenchymal cancers, and potentiate the response to immunotherapy, such as pembrolizumab. The EPOCH study aims to improve our biological understanding of rare cancers driven by EMT and has the potential to change the standard of clinical care for these cancers. It will provide patients with ready access to a combination therapy which otherwise would not be available to them with a higher likelihood for clinical benefit compared to currently available standard chemotherapeutic options.

TRIALS RECRUITING as at 30 June 2023

ADVANCED GYNAECOLOGICAL CANCER

Study	**PEACE**
Title	Palliation in gynae-oncology: patient expectations and assessment of care.
Principal Investigator	Dr Alison Davis
Collaborations	Nordic Society of Gynaecological Oncology – Clinical Trial Unit (NSGO-CTU)-led international trial, ANZGOG lead group for Australia and New Zealand.
Funding	Private Practice Fund Minor Grants
Study Milestones	Planned Sample Size: 73 Planned Number of Sites: 3 Accrual: 4 participants | 3 sites
Contact	john.andrews@anzgog.org.au
Summary  Dr Alison Davis Principal Investigator	The main purpose of this study is to determine the feasibility of collecting information from women with advanced gynaecological cancer about their satisfaction and expectations of care once their disease has become incurable and treatment options more limited or have ceased altogether. It will also assess the feasibility of collecting information from a carer/loved one (if available) as well as collecting details of that care over time. We will gain preliminary insights into participants' satisfaction and expectations of care, but will need to expand the study, assuming feasibility is determined, in order to fully explore these issues fully.

TRIALS IN START UP as at 30 June 2023

ENDOMETRIAL CANCER

Study	**EN.10/TAPER**
Title	A phase II study of tailored adjuvant therapy in pole-mutated and p53-wildtype/NSMP early stage endometrial cancer (RAINBO BLUE & TAPER)
Principal Investigator	Prof Alison Brand AM
Collaborations	Canadian Cancer Trials Group (CCTG)
Funding	Medical Research Future Fund (MRFF) – Clinical Trials Activity Initiative - 2021 Clinical Trials Activity Grant Opportunity – Stream 4
Study Milestones	Planned sample size: 120 Planned number of sites: 10
Contact	lisa.bailey@anzgog.org.au
Summary  Prof Alison Brand AM Principal Investigator	Adjuvant radiotherapy is not always associated with a survival benefit but does have associated toxicities. This single-arm phase II trial will evaluate a molecularly driven, de-escalation adjuvant treatment strategy for POLE-mutated and p53wt/no-specific molecular profile (NSMP) early-stage endometrial cancers. The hypothesis is that de-escalation of adjuvant therapy in patients with POLE-mutated or p53 wildtype (p53wt)/ NSMP endometrial cancer is associated with a low risk of pelvic recurrence, less treatment-related symptom burden and cost savings. The goal of this trial is to change and inform practice, leading to less toxicity for patients and better utilization of health care resources internationally.

TRIALS IN START UP as at 30 June 2023

ENDOMETRIAL CANCER

Study	**XPORT-EC-042**
Title	A Phase 3, Randomised, Placebo-Controlled, Double-Blind, Multicentre Trial of Selinexor In maintenance Therapy After Systemic Therapy for Patients with P53Wild-Type, Advanced or Recurrent Endometrial Carcinoma
Principal Investigator	Assoc Prof Yoland Antill Dr Kate Webber
Collaborations	Karyopharm Therapeutics (Global Sponsor) European Network of Gynaecological Oncological Trial Groups Belgium Gynaecological Oncology Group North-Eastern German Society of Gynaecologic Oncology Multicentre Italian Trials in Ovarian Cancer and Gynaecologic Malignancies Spanish Research Group in Ovarian Cancer The Central and Eastern European Gynaecologic Oncology Group
Funding	Karyopharm Therapeutics
Study Milestones	Planned sample size ANZ: 40 Planned number of sites: 15 (Aus), 1 (NZ) Recruitment open globally, start-up activities ongoing in Australia.
Contact	xport@anzgog.org.au
Summary	Endometrial cancer is one the most common gynaecological malignancy with increasing incidence and associated mortality. Advanced and recurrent endometrial cancer is associated with poor prognosis, including limited disease control for patients who relapse after first-line systemic treatment. TP53 is found in approximately 50% of advanced/recurrent tumours in patients with endometrial cancer. There is a need for targeted therapies for patients with TP53 wild-type endometrial cancer. XPORT is a global, Phase 3 study that plans to enrol up to 220 patients with TP53 who will be randomised 1:1 to receive either a 60 mg, once-weekly, administration of oral selinexor or placebo until disease progression. XPORT was initiated following Karyopharm's SIENDO study which demonstrated a subgroup of patients with TP53 wild-type had better outcomes.

Assoc Prof Yoland Antill

Principal Investigator

TRIALS IN START UP as at 30 June 2023

ENDOMETRIAL CANCER

Study	**DOMENICA**
Title	Randomised phase III trial in MMR deficient endometrial cancer patients comparing chemotherapy alone versus Dostarlimab in first line advanced/metastatic setting
Principal Investigator	Dr Alison Davis
Collaborations	ARCAGY-GINECO
Funding	ARCAGY-GINECO
Study Milestones	Planned sample size: 40 Planned number of sites: 15
Contact	lisa.bailey@anzgog.org.au
Summary  Dr Alison Davis Principal Investigator	There are currently no ongoing trials that can will answer of the question of efficacy of Immune agent alone versus chemotherapy in the group of Mismatch Repair Deficiency (MMRd)/Microsatellite instability-high (MSI-H) endometrial cancer patients in first line setting for advanced/metastatic disease. This trial is a unique opportunity to evaluate Dostarlimab in monotherapy in first line setting for advanced endometrial cancer and to demonstrate in a randomised phase III trial the benefit of Dostarlimab in advanced endometrial MMR deficient cancer versus the standard of care (Paclitaxel and Carboplatin). The goal of the trial is to determine if immune agent treatment alone could be the new standard of care instead of chemotherapy for MMR deficient patients.

TRIALS IN START UP as at 30 June 2023

OVARIAN CANCER

Study	**ROSELLA**
Title	A Phase 3 Study of Relacorilant in Combination with Nab-Paclitaxel versus Nab-Paclitaxel Monotherapy in Advanced, Platinum-Resistant, High-Grade Epithelial Ovarian, Primary Peritoneal, or Fallopian-Tube Cancer.
Principal Investigator	Prof Linda Mileshkin
Collaborations	Global commercial study by Corcept Therapeutics for which ANZGOG conducted feasibility and is acting as consultant and site liaison throughout the study.
Funding	Corcept Therapeutics Inc.
Study Milestones	Planned sample size Australia: 29 Planned number of Australian sites: 10 Recruitment open globally, start-up activities ongoing in Australia.
Contact	charissa.clay@anzgog.org.au
Summary  Prof Linda Mileshkin Principal Investigator	Ovarian cancer is the second most common gynaecologic malignancy. Most patients are asymptomatic until advanced stages of the disease, and for women with distant invasive epithelial ovarian cancer, the 5-year survival rate is approximately 30%. Despite initial therapy, most women will relapse and require retreatment. Patients who develop a recurrence within 6 months of platinum-based therapy are deemed platinum-refractory. There are few treatment options for platinum-resistant ovarian cancer. ROSELLA plans to enrol 360 women globally with recurrent, platinum-resistant ovarian cancer, randomised 1:1 to receive either relacorilant plus nab-paclitaxel or nab-paclitaxel monotherapy. Concept's phase 2 study demonstrated improvements in progression free survival, duration of response and overall survival without increased side effect burden. Corcept's goal with this study is to replicate the positive results shown in the phase 2 study.

TRIALS CLOSED TO RECRUITMENT as at 30 June 2023

OVARIAN CANCER

Study	**ECHO**
Title	A Phase III randomised, controlled trial of exercise during chemotherapy for patients commencing first line treatment for ovarian cancer.
Principal Investigator	Prof Sandi Hayes
Collaborations	Initiated in Australia by ANZGOG in collaboration with the NHMRC CTC and Griffith University
Funding	Cancer Australia/Cancer Council Australia Recruitment support from World Cancer Research Fund (WCRF) Cancer Australia Cancer Council Queensland/Griffith University
Study Milestones	Planned Sample Size: 500 Planned Number of Sites: 11 Actual: 524 participants | 11 sites
Contact	**echo.study@sydney.edu.au**
Summary  Prof Sandi Hayes Principal Investigator	Benefits from exercise may be accrued through improved physical well-being, reduced treatment-related side effects, better treatment adherence, better overall QoL, lower associated health care costs, and perhaps even longer survival. However, there is a lack of evidence and no randomised trials of exercise interventions in ovarian cancer. Observational studies are insufficient to determine cause and effect; randomised trials are needed to provide level one evidence and change clinical practice. This trial will identify whether incorporation of an exercise program into the current standard of care for women undergoing chemotherapy for primary ovarian cancer is a clinically effective and cost-effective way to improve health outcomes in this patient group. Importantly, should it prove cost-effective, translating findings into practice is feasible, since we already have a work-force trained in exercise prescription for special populations (AEPs) and a national funding system that supports the delivery of exercise as a form of treatment (through the Medicare-funded Chronic Disease Care Plan). Findings from this work will address gaps in the literature currently preventing the translation of exercise into standard cancer care.

TRIALS CLOSED TO RECRUITMENT as at 30 June 2023

OVARIAN CANCER

Study	**ICON9**
Title	An international phase III randomised study to evaluate the efficacy of maintenance therapy with olaparib and cediranib or olaparib alone in patients with relapsed platinum-sensitive ovarian cancer following a response to platinum-based chemotherapy.
Principal Investigator	Prof Linda Mileshkin
Collaborations	University College London (UCL)-led international trial, ANZGOG lead group for Australia and New Zealand in collaboration with the NHMRC CTC
Funding	Cancer Australia UCL, U.K. NHMRC Clinical Trials Centre
Study Milestones	Planned Sample Size: 110 (ANZ) | 618 (Globally) Planned Number of Sites: 19 ANZ Actual: 118 randomisations now | 19 sites
Contact	icon9.study@sydney.edu.au
Summary  Prof Linda Mileshkin Principal Investigator	The goal of this international, investigator-initiated, randomised, placebo controlled, double blind Phase III trial is to improve outcomes for patients with recurrent ovarian cancer by investigating the addition of cediranib to olaparib maintenance therapy following completion of platinum-based chemotherapy for platinum-sensitive relapsed ovarian, fallopian tube or primary peritoneal cancer.

TRIALS CLOSED TO RECRUITMENT as at 30 June 2023

OVARIAN CANCER

Study	**SOLACE2**
Title	A Phase II randomised trial comparing immune priming by low dose oral cyclophosphamide plus olaparib versus priming by olaparib alone, prior to combination therapy with olaparib plus durvalumab, versus single agent olaparib alone, in asymptomatic platinum-sensitive recurrent ovarian, fallopian tube or primary peritoneal cancers with homologous recombination repair defects.
Principal Investigator	Prof Clare Scott AM Assoc Prof Chee Lee (Co-Chair), Prof Michael Friedlander AM (Co-Chair)
Translational Chair	Prof Magdalena Plebanski
Collaborations	Initiated in Australia by ANZGOG in collaboration with the NHMRC CTC, RMIT and WEHI
Funding	AstraZeneca
Study Milestones	Planned Sample Size: 114 Planned Number of Sites: 15 Actual: 114 participants | 15 sites
Contact	**solace2.study@sydney.edu.au**
Summary  Prof Clare Scott AM Principal Investigator	The SOLACE2 trial is a multi-centre randomised Phase II investigator-initiated trial with the aim of investigating different strategies to prime the immune system to enhance response to olaparib in women with asymptomatic platinum-sensitive recurrent ovarian, fallopian tube or primary peritoneal high grade serous cancers at the time of the first CA125 serum marker rise. Women are randomised to receive either olaparib or olaparib plus oral cyclophosphamide for three months before being treated with olaparib and durvalumab. A control arm of olaparib only treatment will be used to examine for comparative differences. The study will recruit women with and without BRCA mutations. The primary endpoint of this trial is progression-free survival, with other secondary and extensive translational endpoints.

TRIALS CLOSED TO RECRUITMENT as at 30 June 2023

OVARIAN CANCER

Study	**STICs and STONEs**
Title	A randomised phase II double-blind placebo-controlled trial of acetylsalicylic acid (Aspirin) for prevention of ovarian cancer in women with BRCA1 and BRCA2 mutations.
Principal Investigator	Prof Kelly-Anne Phillips
Collaborations	Canadian Cancer Trials Group (CCTG)-led international trial, ANZGOG lead group for Australia and New Zealand in collaboration with the NHMRC CTC
Funding	NHMRC Clinical Trial Centre Project Grant Support from Canadian Cancer Trials Group (CCTG)
Study Milestones	Planned Sample Size: 70 (ANZ) | 414 (Globally) Planned Number of Sites: 6 ANZ Actual: 37 participants | 6 sites
Contact	**stics.study@sydney.edu.au**
Summary  Prof Kelly-Anne Phillips Principal Investigator	Women with a BRCA1 or BRCA2 gene abnormality are at increased risk of ovarian and fallopian tube cancers and often have their ovaries and tubes removed to prevent cancer. Microscopic cancers are sometimes seen at the time of this surgery. Some studies have suggested aspirin might reduce the risk of developing ovarian and fallopian tube cancers, but this is uncertain because the design of the previous studies were not optimal. The STICs and STONEs study will assign women with a BRCA1 or BRCA2 gene abnormality to daily aspirin or placebo for at least 6 months and no more than 24 months before their preventive surgery. We expect to see fewer cancers at the time of preventive surgery in the group of women that is assigned to aspirin compared with those assigned placebo. The study will provide a better understanding of how ovarian and fallopian tube cancers start and whether aspirin might be a useful prevention agent.

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is the peak national gynaecological cancer research organisation.
We are recognised as a world leader in clinical trials research.

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