

Editorial

Welcome to the new combined ANZGOG Trials Newsletter. This new format has been introduced following a review of the contact we have with our sites. One of the benefits of this combined newsletter is that sites can get an overview of all current ANZGOG trial activity. This may result in some sites asking to join a study as a new site or sites being aware of where a referral can be directed for a study that has limited site numbers.

ANZGOG's portfolio of trials now covers all stages of the life cycle of a clinical trial. Our two USGOG trials are both closed to recruitment, we have several trials open to recruitment, our first ICON-7 sites have just opened, and others are still in the planning stage.

I'd like to make a special mention of TRIPOD. The original TRIPOD concept was discussed at the Noosa meeting in 2006 following on from the Clinical Alert from the NCI that intraperitoneal chemotherapy was the preferred treatment for advanced ovarian cancer patients. We now have three sites activated and we have just recruited our first patient! This is great news after a long and winding road to get to this point.

Trial staff at the CTC work hard to assist sites with clinical questions. If you have any questions about patient eligibility, treatment modification, or response criteria then please contact the relevant trial coordinator who will then discuss your questions with the study PI.

The ANZGOG Annual General Meeting will be held in Adelaide in November 2007, immediately prior to COSA.

The program for the Study Coordinators Forum has not yet been confirmed but details will follow at a later date.

Many of you will have met with the ANZGOG/AGITG Quality Assurance Audit Coordinator, Karen Pinto. Karen conducts audits at the ANZGOG Coordinating Centre and at study sites, and she places a strong emphasis on continuous improvement and education.

Finally, please do keep an eye on our own website www.anzgog.org.au There is lots of trial specific information there and we will continue to add new items. The study coordinators mentoring program can also be accessed via the website.

We hope you enjoy this new newsletter format. You will shortly also be receiving an ANZGOG Group newsletter with more information about other group activities including forthcoming meetings.

Please send us your feedback, we really want to make our communication with our sites as useful as possible.

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Editors:

Julie Martyn and Kim Gillies

Your ANZGOG team!



Back Row: Ray Tangunan, Julie Martyn, Hannah Paterson, Wendy Hague (CTC Clinical Trials Programme Director), Corona Gainford (Clinical Research Fellow)
Front Row: Kim Gillies, Chris Aiken and Helen Mueller
Absent: Ayanthi Salgado (Operations Manager), Lucky Waniganayake, Kerri Carlton

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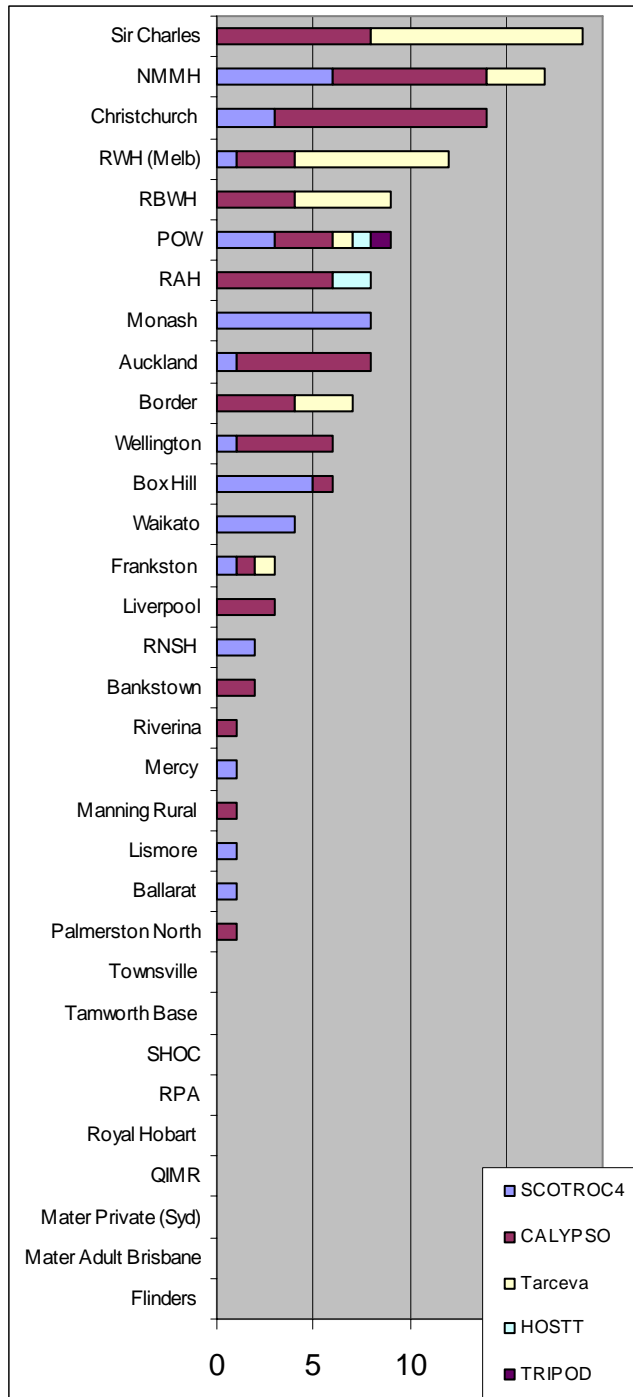
TRIPOD

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PORTEC3

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Accrual by site across all active trials



Congratulations to Dr Martin Buck and his team at Sir Charles Gairdner Hospital for being our highest recruiting site at present, with Newcastle Mater not too far behind. The efforts of all of our sites are very much appreciated.

New Trials

PORTEC3: Randomised Phase III trial comparing concurrent chemoradiation and adjuvant chemotherapy with pelvic radiation alone in high risk and advanced stage endometrial carcinoma. PI: Linda Mileschkin

This is a prospective, multicenter, randomized Phase III Intergroup trial of the Dutch Cooperative Gynecologic Oncology Group and the Endometrial Subgroup of the UK National Cancer Research Institute. In this trial, 500 patients with either FIGO stage I or 2 endometrial adenocarcinoma with high-risk features or stage 3 endometrial carcinoma who meet the inclusion criteria will be randomised to receive either external beam pelvic radiotherapy (control arm) or concurrent radiotherapy and chemotherapy followed by chemotherapy (experimental arm).

We have received a very encouraging response to our call for expressions of interest in this study and we are currently following up with interested sites.

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SYMPTOM BENEFIT: Does Palliative Chemotherapy Improve Symptoms in Women with Recurrent Ovarian Cancer? PI: Michael Friedlander.

This is a prospective observational cohort study in women with platinum resistant / refractory ovarian cancer who are about to commence chemotherapy. The eventual aim is to develop a better measure of benefit from palliative chemotherapy that can be used in clinical trials. This GCIG study will be conducted in collaboration with PoCoG and will be run in two stages. The NCIC will participate in stage I and other GCIG groups will join in Stage 2.

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CALYPSO

Recruitment to this trial is due to close within days. While this has been a great effort, our total of 71 is well behind our accrual target of 150 patients. We will be following up with a post-recruitment survey.

Data Management

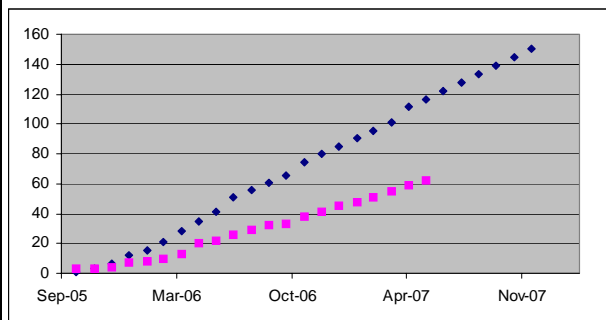
Please remember to validate eCRFS once they are complete and you have checked your entries. For sites using paper CRFs, once again, please submit these to the CTC in a timely manner.

Disease Evaluation

It is a requirement of this trial that you adhere to the disease evaluation schedule provided at randomisation. Adherence to the schedule will avoid protocol violations.

Hospital	Date Activated	Patients recruited
Christchurch Hospital	13/01/2006	11
Newcastle Mater Misericordiae Hospital	5/10/2005	8
Sir Charles Gairdner Hospital	18/01/2006	8
Auckland Hospital	4 /05/2006	7
Royal Adelaide Hospital	12/07/2006	6
Wellington Hospital	23/03/2006	5
Border Medical Oncology	21/12/2005	4
Royal Brisbane and Women's Hospital	1/11/2005	4
Royal Women's Hospital	21/03/2006	3
Liverpool Hospital	12/07/2006	3
Prince of Wales Hospital	13/10/2005	3
Bankstown-Lidcombe Hospital	22/11/2005	2
Manning Rural Referring Hospital	4 /01/2006	1
Riverina Cancer Care Centre	21/11/2006	1
Frankston Hospital	19/10/2005	1
Box Hill Hospital	30/11/2005	1
Palmerston North Hospital	16/06/2006	1
Royal Hobart Hospital	14/12/2005	0
Monash Medical Centre	29/03/2006	0
Mater Private Hospital	12/04/2006	0
Flinders Medical Centre	19/04/2006	0
Royal Prince Alfred Hospital	09/03/2007	0

PUBLICATIONS: An abstract of the interim analysis of results from the first 200 patients has been accepted for a poster presentation at the European Society for Gynaecological Oncology meeting in Berlin in October. This abstract lists Tony Bonaventura from Newcastle Mater as an ANZGOG author, as his site contributed the most patients to that 200; Val Gebiski from the CTC is also listed as the study statistician. The CTC is the statistical coordinating centre for this trial.



A big welcome to Kerri who starts as the new CALYPSO trial coordinator on Sept 18th!

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GOG182

The GOG 182 study is a collaborative group study conducted by the United States Gynaecologic Oncology Group. Its purpose was to compare the efficacy of four experimental chemotherapy regimens individually against a control arm of paclitaxel and carboplatin. Patients recruited to this trial had a histologic diagnosis of primary peritoneal carcinoma or epithelial ovarian carcinoma, Stage III or IV, with either optimal or suboptimal residual disease following initial surgery. All patients must have had appropriate surgery for ovarian or peritoneal carcinoma with appropriate tissue available for histologic evaluation to confirm diagnosis and stage. The primary analysis of overall survival, which was performed in May 2006, indicated that none of the experimental regimens are superior to the control regimen.

Q Forms

Please ensure your patients are followed up for their scheduled appointments and all QForms are completed.

GOG 182

Opened to recruitment:
June 2002

Closed to recruitment:
Sep 2004

183 patients recruited in ANZ
across 26 sites.

Patients are followed-up for life

GOG 182

We will shortly be returning all pathology slides and blocks to centres as these are no longer able to be retained at the CTC.

GOG199

The priority for GOG199 at the moment is improving on issues to do with the translational research component of this study. The collection, processing, labelling and shipment of specimens and the accompanying SP Forms and shipping manifests are extremely important. Through close attention to protocol procedures, high quality specimens can be produced. Careful labelling of samples and careful attention to shipping manifest and SP forms will ensure that the samples are processed. The Tissue Bank cannot process information that is missing or incomplete whether it is on the specimen label or accompanying documentation. Mislabelled samples will end up being destroyed if they cannot be identified. As well as reducing the number of sample discrepancies ANZGOG is also working to improve the shipment procedures of GOG 199 samples so that specimens are shipped as close as possible to the required due date as GOG requests. This will involve working in consultation with the data managers at site and the ABN tissue bank in Melbourne. I would like to thank all the sites for their hard work and patience during this complex and labour intensive trial.

Crossing over

Women who were enrolled in the screening arm of this study can choose to cross over to the surgery arm. Remember to have them complete the DM0199 form prior to surgery, and fax the FFS#2 form to us here at the CTC on the day of surgery.

Our very best wishes to Hannah who goes on maternity leave on October 5. The GOG studies will then be looked after by Kim Gillies.

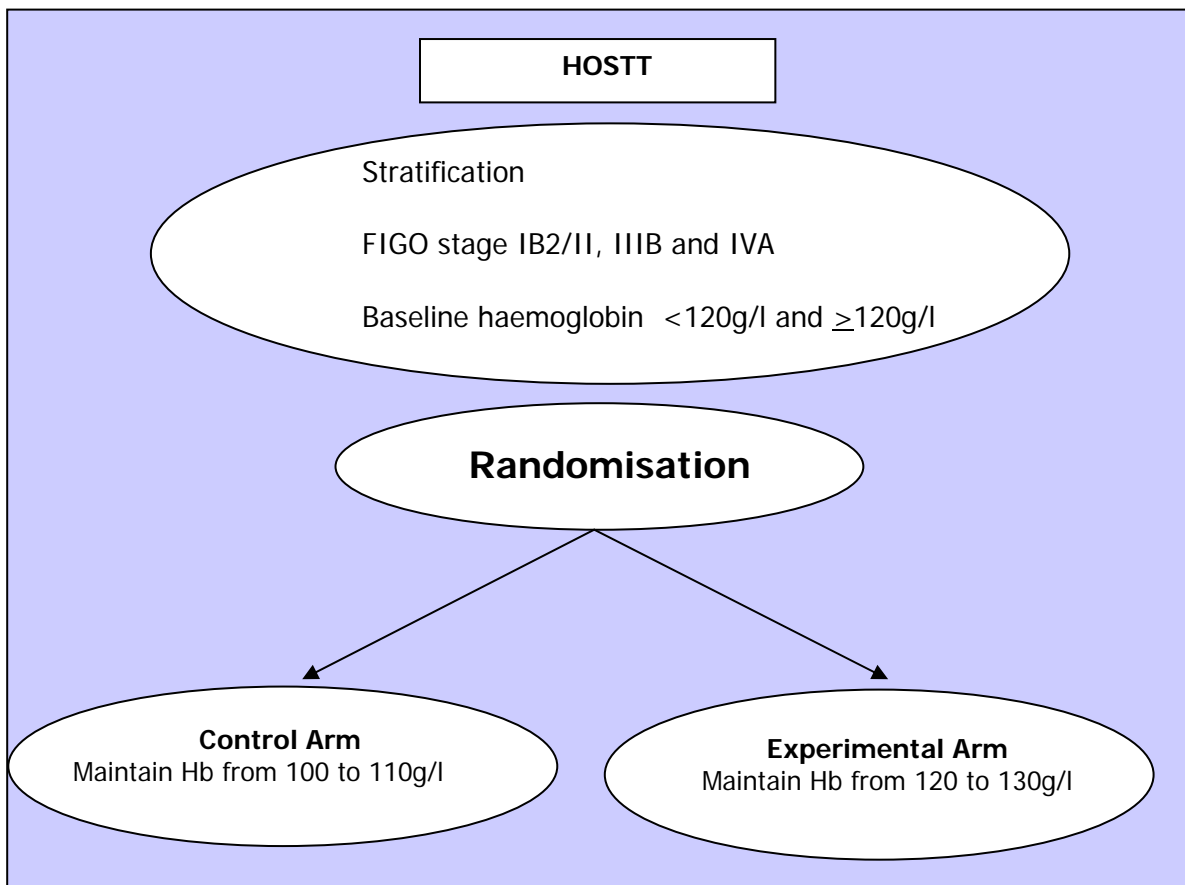
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HOSTT

A phase II/III study to evaluate the impact of maintaining haemoglobin levels above 120g/L versus above 100g/L in anaemic patients with carcinoma of the cervix receiving concurrent cisplatin and radiation therapy.

Currently there are five sites open to recruitment in Australia and three patients recruited. Contractual negotiations are well underway with Taiwan, who expect to recruit significant numbers of patients to this study, and there are additional centres in Australia and New Zealand still to join.



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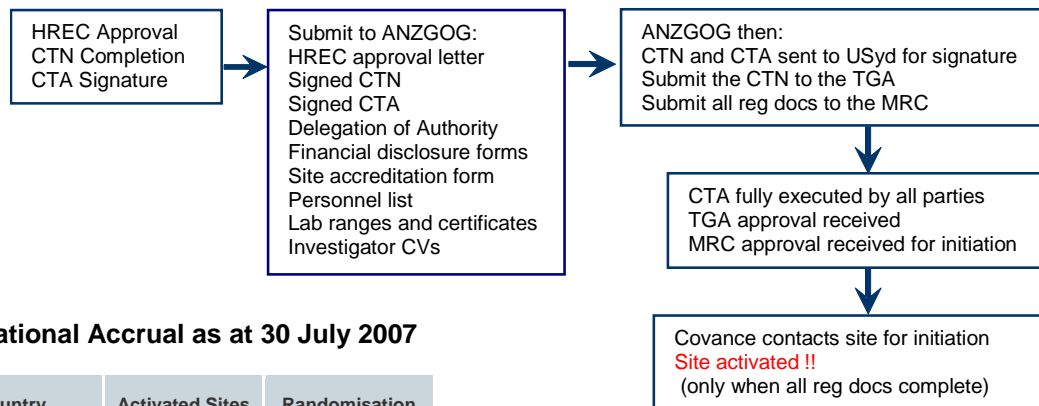
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ICON7

ICON7 is a randomised (1:1 ratio), 2 arm, multi-centre, GCIG open-label phase III trial designed to evaluate the safety and efficacy of adding bevacizumab, a humanised monoclonal antibody against Vascular Endothelial Growth Factor (VEGF), to standard chemotherapy with carboplatin and paclitaxel.

We are very pleased to announce that the first study initiation visits have been carried out by Covance, with Border Medical Oncology and Royal Adelaide Hospital now activated. We hope to have our first patient randomised soon!

STEPS TO SITE ACTIVATION



International Accrual as at 30 July 2007

Country	Activated Sites	Randomisation
Australia	0	0
Canada	4	1
Denmark	3	2
Finland	2	1
France	33	24
Germany	63	55
New Zealand	0	0
Norway	0	0
Sweden	0	0
United Kingdom	25	50
TOTAL	130	133

ANZ target accrual = 100
Total accrual = 1520

ANZGOG - 2 active sites (19th September 2007)

In line with GCP regulations, ANZGOG will be informing PIs of any SUSAR that has occurred on the ICON7 Trial.

The SAE form with details of the SUSAR will be found on the ICON7 website (<http://www.icon7trial.org>) in the secure Collaborators area.

All individual logins and passwords have now been distributed for access by trial staff to member-restricted areas – if you have misplaced this information, please contact either Helen or Kim at the CTC.

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SCOTROC4

Justin Simard-Lebrun is currently on maternity leave and Raymond Tangunan has taken over the role of Trial Coordinator.

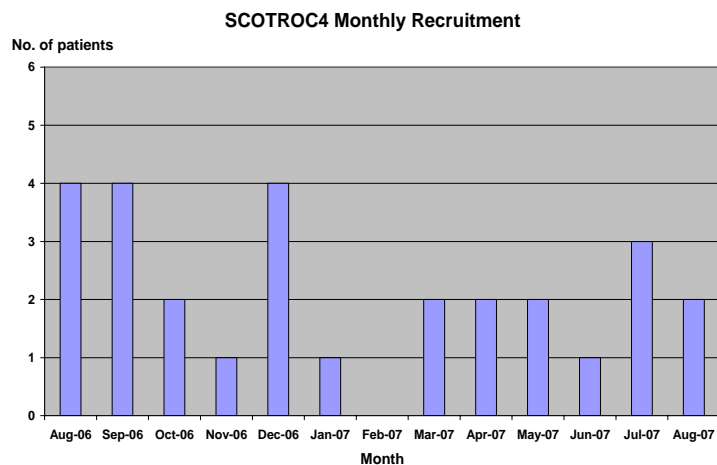
As of the end of August, SCOTROC4 has recruited **38 patients** in Australia and New Zealand, and a total of **689 patients** recruited internationally. **15 out of our 24 active centres have recruited patients.**

Please ensure to contact us if you have any recruitment concerns (e.g. protocol eligibility criteria, screening, resources, etc).

Accrual by site

Auckland	1
Ballarat	1
Border	0
Box Hill	5
Christchurch	3
Frankston	1
Lismore	1
Liverpool (pending)	
Manning Base	0
Mater Adult Brisbane	0
Mercy for Women	1
Monash	8
Newcastle Mater	6
Prince of Wales	3
Royal Brisbane	0
Royal Hobart	0
Royal North Shore	2
Royal Women's	1
SHOC	0
Tamworth Base	0
Townsville	0
Waikato	4
Wellington	1
Westmead (Pending)	
Total	38

Accrual per month



Invoice requests will be sent to sites that have randomised eligible patients in the period from 1st January and 30th June 2007.

We look forward to activating Westmead and Liverpool Hospitals in the not-too-distant future

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EORTC 55041—TARCEVA

A randomised, multicentre, phase III study of Erlotinib versus observation in patients with no evidence of disease progression after first line, platinum-based chemotherapy for high-risk Stage I and Stage II-IV ovarian epithelial, primary peritoneal, or fallopian tube cancer.

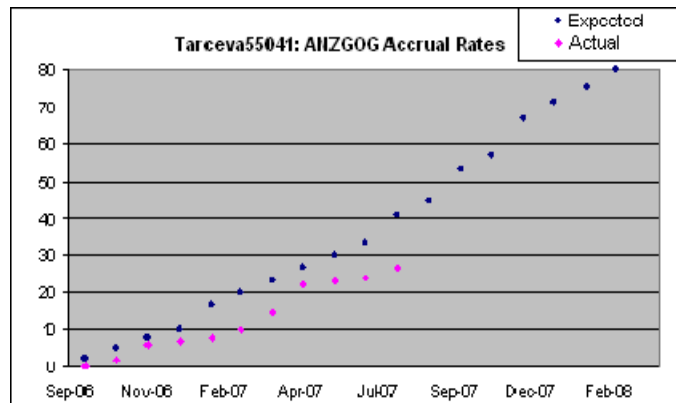
Recruitment status as at late Aug'07: ~616. Close to 74% of target accrual (830).

Sites are up to date with CRF submission. Initial site payments (for randomisation \$400/per patient) are underway. Sites are requested to forward a copy of their HREC annual report approval & 11th Edition IB approval letters.

CRF completion notes:

Treatment/Observation Form5
Q55: to be completed for patients on both arms

End of Treatment Form6
Complete when a patient withdraws from treatment (< 2yrs), then during subsequent visits complete only the **Follow-up Form7**



Site	Total at Sept 14
Newcastle Mater	3
Manning Rural	
Tamworth	
Royal Brisbane	5
Royal Women	8
Border Medical	3
Frankston	1
Prince of Wales	1
Sir Charles Gairdner	11

New sites:

Christchurch, Palmerston North, Canberra and Westmead have all submitted to Ethics. We look forward to having these sites participating soon.

Total

32

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TRIPOD

Tripod is a 'home grown' ANZGOG study and is the first IP study to be conducted in Australia and New Zealand. We believe it is currently the only study worldwide evaluating IP chemotherapy in ovarian cancer patients. Our accrual target is a minimum of 35 and a maximum of 100 recruitments.

Amendment 1 Version 2 (29 May 2007) was sent out to sites on the 10th August 2007 along with PIC Version 3 (11 May 2007). Please submit Amendment 1 to your local HREC.

The main changes to the protocol are:

- Addition of the IP Distribution sub-study
- Patient Preference sub-study

The TRIPOD trial has been registered with the Australian Clinical Trials Registry (ACTR) - registration no. 2606000502538 Further information regarding the ACTR can be found at <http://www.actr.org.au/>

NEWSFLASH

**1st TRIPOD
patient
registered!**

Sites involved in the TRIPOD trial

Border Medical Oncology Canberra Hospital Christchurch Hospital Coffs Harbour Flinders Medical Centre Liverpool Hospital Mater Adult Brisbane Mercy Hospital For Women Prince of Wales Hospital* Royal Adelaide Hospital* Royal Hobart Hospital Royal North Shore Hospital	Royal Prince Alfred Hospital - Sydney Cancer Centre Royal Women's Hospital* Sir Charles Gairdner Hospital St George Hospital Townsville Hospital - Townsville Cancer Centre Wellington Hospital Westmead Hospital
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* Active sites

Ethics approval is the main factor holding up the recruitment of new sites. Please let us know if there is anything we can do to assist with obtaining HREC approval.

We have recently been advised that the BARD intraperitoneal ports will no longer be sold in Australia after October 2007, however Portacath ports are still available.

Schema

- Single arm, multi-centre Phase II
- 35-100 patients
- Endpoints: Feasibility, safety, quality of life

Eligible consenting patient with catheter inserted

Registration

Day 1 IV Paclitaxel 135mg/m²
Day 2 IP Cisplatin 75mg/m²
Day 8 IP Paclitaxel 60mg/m²

6 cycles q 3 weekly

Follow up every 3 months for 2 years

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