ARTemis: Avastin® Randomised Trial with neo-adjuvant chemotherapy for patients with early breast cancer

ARTemis Newsletter Issue 2 Dec 2009

Welcome to our second edition. In this newsletter, we will keep you updated on all current trial information, participating sites, recruitment, the launch meeting and details of the trial sub-studies.
We will also draw your attention on the closure of the randomisation service over the Christmas holiday.

ARTemis TRIAL

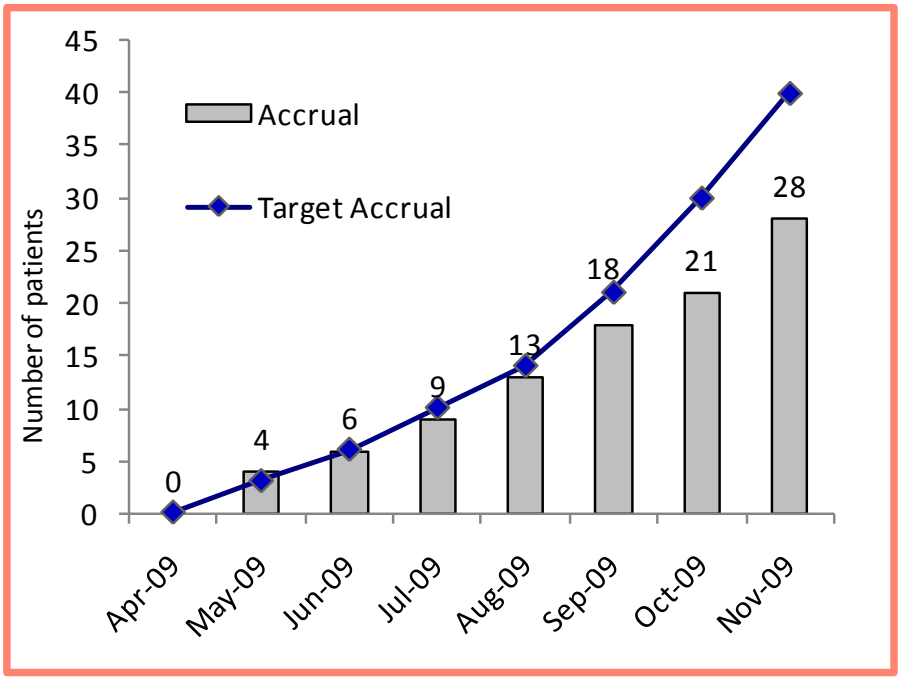
A phase III, randomised trial to determine whether the addition to neo-adjuvant chemotherapy of an anti-angiogenic agent bevacizumab is more effective than standard chemotherapy alone in terms of short-term and long-term outcome in patients presenting with HER2-negative early breast cancer. ARTemis is a randomised (1:1), multi-centre, phase III, open-label trial.

LAUNCH MEETING

The ARTemis Launch Meeting on 10 November was a big success: with **66 delegates attending from 34** sites. Feedback from sites where very positive, attendees generally found the morning very informative and particularly enjoyed the informal afternoon discussions which generated much audience participation. By attending the meeting 31 PIs, Research Nurses and Pharmacists were signed off for their initiation training.

PATIENT RECRUITMENT

Total Number of Patients Recruited: 28



All data correct as on 30 Nov 2009

The Randomisation Service will close on Wednesday 23 December at 12 noon and re-open on Monday 4 January at 9 am

Open Centres with number of patients recruited

Addenbrookes Hospital (1/4/09) 23
Western General Hospital, Edinburgh (1/9/09) . 4
Peterborough District Hospital (24/9/09)..... 1
Barts & the London (23/11/09) 0
Guy's Hospital (24/11/09) 0
The Royal Surrey County Hospital (6/9/09)..... 0

Centres to be open soon!!!

Bedford Hospital NHS Trust
Charing Cross Hospital
Christie Hospital
Essex County Hospital
Royal Bournemouth Hospital
St James's University Hospital
St Mary's Hospital, London
Torbay District General Hospital

Centres expressed interest to participate

Aberdeen Royal Infirmary
Beatson West of Scotland Cancer Centre
Blackpool Victoria Hospital
Burnley General Hospital
Cheltenham General Hospital
Chorley District General Hospital
City Hospital
Clatterbridge Centre for Oncology
Crosshouse Hospital
Falkirk Hospital
Freeman Hospital, Newcastle
Furness General Hospital
Glan Clwyd Hospital
Gloucester Royal Hospital
Hereford County Hospital
Kidderminster Hospital
Leicester Royal Infirmary
Medway NHS Foundation Trust
Nevill Hall Hospital
New Cross Hospital
Newham Hospital
Ninewells Hospital
North Middlesex Hospital
Nottingham University Hospital
Poole Hospital
Princess Alexandra Hospital
Queen Elizabeth Hospital, King's Lynn
Queen's Hospital, Burton on Trent
Royal Blackburn Hospital
Royal Glamorgan Hospital
Royal Gwent Hospital
Royal Hampshire County Hospital
Royal Lancaster Infirmary
Royal Preston Hospital
Royal United Hospital
Singleton Hospital
Southampton General Hospital
Southend University Hospital
Southport and Formby District General Hospital
St John's Hospital
UCLH Hospital NHS Foundation Trust
University Hospital Coventry & Warwickshire
Velindre Hospital
Warrington & Halton Hospitals NHS Foundation Trust
West Middlesex University Hospital
West Suffolk Hospital
Worcestershire Royal Hospital
Yeovil Hospital

Thank you to all centres for your continued efforts on setting up sites.

ARTEMIS TRANSLATIONAL RESEARCH (ARTEMIS-SCIENCE)

Fresh tissue sub-study:

We are looking to collect fresh tissue samples in 200-300 patients for DNA, RNA and miRNA isolation.
When: Before patients start their chemotherapy as well as at the end of their chemotherapy / time of surgery, and where possible, midway through chemotherapy.
How: Different centres collect tissue in different ways! Pre-chemo could be obtained at the time of clip insertion, freehand at the time of a sentinel lymph node biopsy or at the same time as the first pre-chemo ultrasound. Midway could be taken when the midway ultrasound is done and post chemo could be taken from the surgical specimen to save patients undergoing an extra biopsy.
Storage: Tissue can be placed directly into vials of RNA-later solution which can then be posted through the royal mail postal system (all equipment and postage supplied by the trials team). If preferred, and you have access to a -80°C freezer, tissue can be stored at your centre and we can arrange a courier.
Help: The Cambridge translational team can come to visit to help set this up in your centre. We have lots of experience with fresh tissue collection. For more information please contact: Linda Jones, Senior Research Sister (01223) 256422 or email: laj28@cam.ac.uk.
Please do consider taking part in this important sub-study

Sequential bloods sub-study (open soon):

We are looking to collect blood samples in 100-200 patients to determine if circulating angiogenic markers can be used to predict bevacizumab benefit.
When: Pre-chemotherapy, after cycle 1, after cycle 2, after cycle 4, and pre-surgery.
How: These bloods samples can be collected at the same time as routine pre-chemo bloods; they will need centrifuging and some pipetting – all SOPs and kits will be provided.
Storage: Frozen at -80°C on site (or -20°C if not available); and the translational team will arrange for courier collection.

Mandatory tumour blocks:

We are collecting paraffin-embedded formalin-fixed tumour blocks in all 800 patients for analysis of the trial's primary endpoint – pathological response.
When: Diagnostic tumour block, and surgery blocks and slides are requested retrospectively.
How: The translational team will request these directly from your Pathology department.
Help: Louise Grybowicz, Trial Coordinator: (01223) 348447, or email: louise.grybowicz@addenbrookes.nhs.uk

Mandatory single blood sample (open soon):

We are collecting a single blood sample from all 800 patients for DNA isolation.
When: Once, anytime while the patient is on-study – taken at the same time as routine bloods
Storage: Posted directly to the Cambridge translational office: kit, SOPs & postage supplied.
Help: Louise Grybowicz, Trial Coordinator: (01223) 348447, or email: louise.grybowicz@addenbrookes.nhs.uk

HER-2+ patients : Be aware these **neo-adjuvant** patients can be randomised into *PERSEPHONE*: chemotherapy with concomitant or sequential Herceptin® for 6 or 12 months. For more details, please contact Anne-laure.vallier@addenbrookes.nhs.uk

Persephone

Phase III Trial

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Pharmacovigilance and Translational Studies

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