

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

Welcome to our first ARTEMIS newsletter, which is full of the latest news and information on the Trial which started in April 2009.

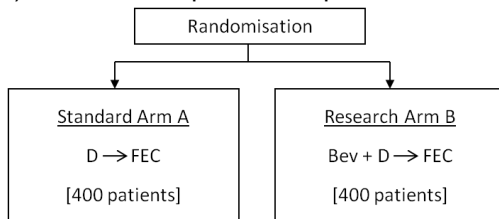
In this newsletter, we will update you with trial information, participating sites, recruitment, site set-up/activation procedures and details of the trial launch meeting.

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. Associated translational science will aim to identify molecular markers that predict for benefit (or lack thereof) of addition of bevacizumab to conventional chemotherapy, profiling paraffin-embedded and fresh tissue, and blood samples for response/resistance. Quality of Life sub-studies will collect data critical to any future health technology assessment of bevacizumab in this indication.

DESIGN AND TREATMENT

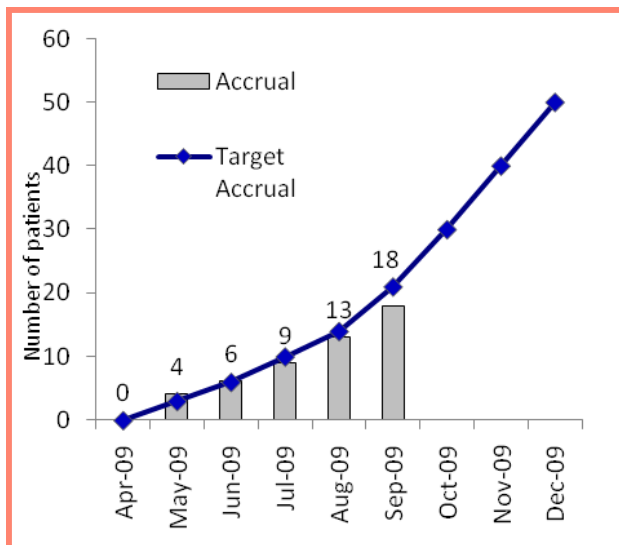
Randomised (1:1), multi-centre, phase III, open-label trial.



PATIENT RECRUITMENT

Total Number of Patients Recruited: 18

We require 50 patients by end of 2009 and more sites to be open soon. We need your help to achieve this target.



All data correct as on 01 Oct 2009

Our special thanks to Addenbrooke's Hospital who recruited highest number of patients so far.



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Open Centres with number of patients recruited
Addenbrookes Hopsital (1/4/09)..... 18
Peterborough District Hospital (24/9/09)..... 0
The Royal Surrey County Hospital (6/9/09)..... 0
Western General Hospital, Edinburgh (1/9/09) . 1

Centres to be open soon!!!

Barts & the London
 Bedford Hospital NHS Trust
 Charing Cross Hospital
 Christie Hospital
 Essex County Hospital
 Guy's Hospital
 Royal Bournemouth Hospital
 St James's University Hospital
 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
 Clatterbridge Centre for Oncology
 Crosshouse Hospital
 Falkirk Hospital
 Freeman Hospital, New Castle
 Furness General Hospital
 Glan Clwyd Hospital
 Gloucester Royal Hospital
 Hereford County Hospital
 Kidderminster Hospital
 Leicester Royal Infirmary
 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
 St Mary's Hospital, London
 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.

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



SITE SET-UP/ACTIVATION PROCEDURE

We have provided you with all study documents required for submissions at your site. In order to activate your site, we also require completion of following documents.

1. Fully completed and original Registration Forms, Site Signature and Delegation Log & Pharmacy staff Log
2. Patient Information Sheets and Consent Forms and GP letter on your trust headed paper
3. CV & evidence of GCP Training for PI
4. CV for Co-Investigator(s) and Lead Pharmacist
5. Fully signed original Participating Site Agreement (two copies)
6. Local R & D Approval Letter and ARSAC Approval Letter (if applicable)

We will also provide you with an Investigator Site File and Pharmacy File and arrange initiation training (teleconference or on-site) with PI, Research Nurse(s) and Pharmacy before your site activation.

Once initiation procedures complete and all documents are in place, we will open your site to patient recruitment.

ARTEMIS Trial Launch Meeting

Tuesday, 10 November 2009

The King's Fund, London

ARTEMIS trial launch meeting will be held at The King's Fund in London on **10 November 2009**. We invite all participating site study staff to attend this meeting. We have invited speakers from the ARTEMIS TMG and Roche who will discuss ARTEMIS and one of the trial drug Avastin® in detail. ARTEMIS will be discussed over four different sessions from 9.45 am to 15.00 pm as below:

- ▶ **Neo-adjuvant treatment for breast cancer trial: a real team work** To discuss ARTEMIS from the oncologist's, radiologist's, surgeon's and pathologist's perspectives.
- ▶ **Avastin and ARTEMIS Trial** Roche will talk about breast cancer trials and Avastin® and TMG will discuss clinical and translational aspect of the ARTEMIS trial.
- ▶ **Trial Management** will involve trial set-up, initiation, CRFs, Pharmacy issues, expected toxicities and Pharmacovigilance of ARTEMIS.
- ▶ **Translational sub-studies** will involve practicalities of this part of the trial.

Attendance at the launch meeting will count towards a part of our trial initiation procedures, therefore sites attending this meeting may not need an initiation visit / teleconference. We encourage all trial team members (PI, Co-Investigators, Pathologist, Radiologist, Research Nurses, Pharmacists and a Main Contact) at your site to attend this meeting in order to speed up the set-up procedure. Please register by Monday 02 November 2009.

We are happy to repeat this training again over the phone or on site, if your site require / requested. It is our responsibility to make sure that all participating site personnel are well trained on ARTEMIS before we activate your site for patient recruitment.

For registration and more information about the Launch Meeting please contact the ARTEMIS team at Warwick CTU or Cambridge CCTC.

HAPPY TO HELP!!! ARTEMIS TEAM CONTACT DETAILS

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