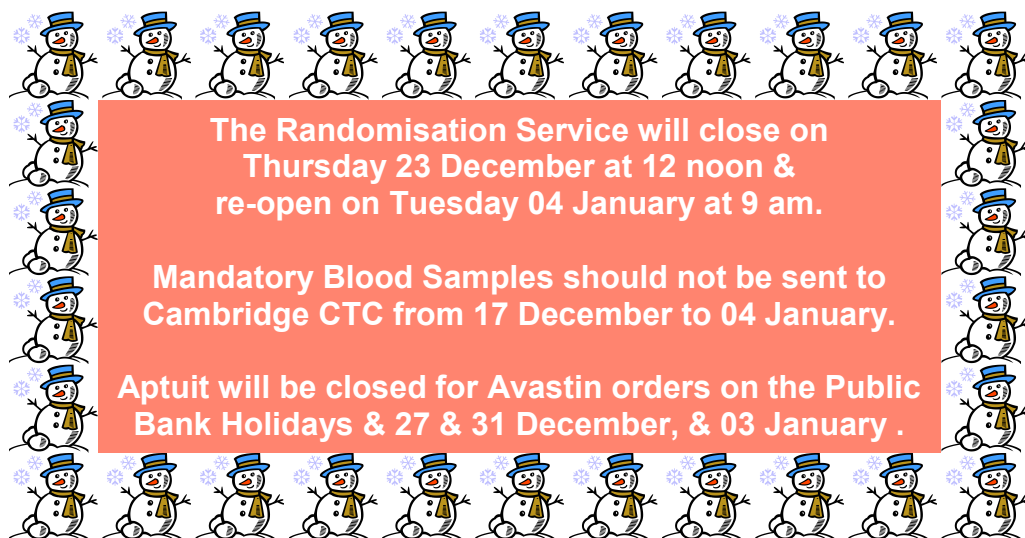


ARTemis: Avastin® Randomised Trial with neo-adjuvant chemotherapy for patients with early breast cancer

ARTemis Newsletter Issue 5 December 2010

Welcome to our fifth edition. This newsletter will keep you updated on service over the holiday break, recruitment figures, safety issues, and sub-studies.



The Randomisation Service will close on Thursday 23 December at 12 noon & re-open on Tuesday 04 January at 9 am.

Mandatory Blood Samples should not be sent to Cambridge CTC from 17 December to 04 January.

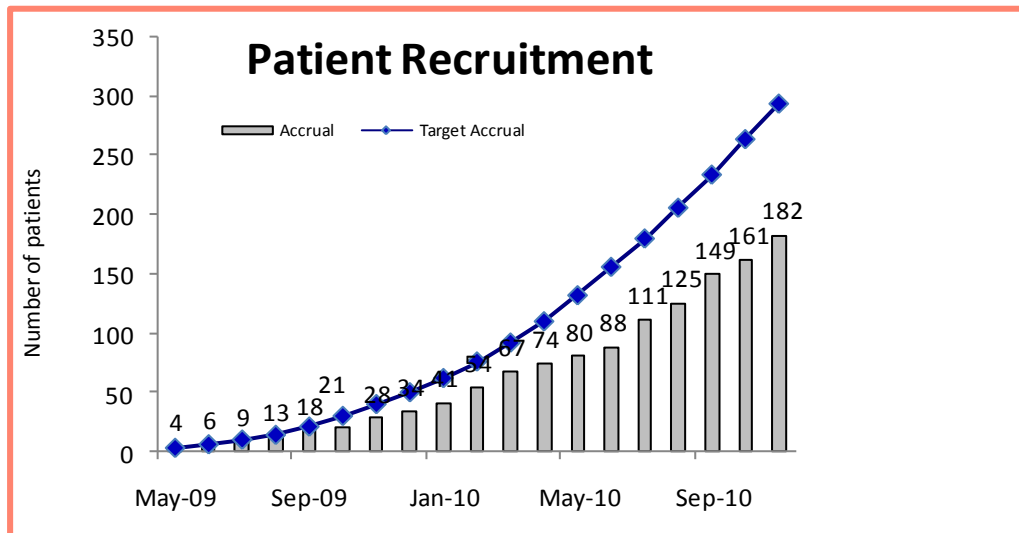
Aptuit will be closed for Avastin orders on the Public Bank Holidays & 27 & 31 December, & 03 January.

PATIENT RECRUITMENT: Number of Patients Recruited: 182

We are doing well with 42 centres open for recruitment, 2 over our target for this stage of the trial.

We are now reaching 200 patients but are still under target. Recruitment has really improved but we still need your continuous support to reach 200 patients by the New Year. We are very grateful to you for your hard work in approaching patients. Please continue actively screening and randomising more patients into the study.

All data correct as on 30 November 2010



TIME WINDOWS:

It is in the very best interest of patients to receive their treatment as soon as possible after diagnosis. Please pre-book the investigations as early as possible to help reduce the time window (even before HER2 results).

Some sites have reported difficulties in being able to randomise their patients within 4 weeks of the diagnostic biopsy date: it is very important for the trial, and to the great benefit of your patients that randomisations are made within 4 weeks of the diagnostic biopsy, and treatment started as early as possible. We have found that booking screening investigations which have a long waiting list e.g. ECHO, as early as possible; for example when a patient is identified at MDT meetings, or when she has show an interest in the trial, reduces the waiting time and the patient can consent to the trial in the interim. As always please contact the trial office if you are having any problems with recruitment or timelines – we may have some suggestions to help!

Centres open

Addenbrooke's Hospital	50
Western General Hospital	20
Charing Cross Hospital	11
Peterborough District Hospital	10
West Middlesex Hospital	9
St James's University Hospital	9
St Bartholomew's Hospital	8
Royal Surrey County Hospital	7
Christie Hospital	7
Royal Bournemouth Hospital	5
Torbay District General Hospital	5
St Mary's Hospital (London)	3
Essex County Hospital	3
City Hospital (Sandwell)	3
UCLH (London)	3
University Hospital Coventry	3
New Cross Hospital	3
Nottingham University Hospital	3
Newham Hospital	2
Aberdeen Royal Infirmary	2
Royal Hampshire County	2
Maidstone Hospital	2
Bedford Hospital	2
Glan Clwyd Hospital	2
King's College Hospital	2
Guy's Hospital	1
Queen's Hospital (Burton)	1
St John's Hospital	1
Royal Liverpool University	1
Southend University Hospital	1
Macclesfield District Hospital	1
Southampton General Hospital	0
Clatterbridge Centre for Oncology	0
Royal Glamorgan Hospital	0
Southport Hospital	0
Newcastle Upon Tyne Hospitals	0
North Middlesex Hospital	0
Warrington & Halton Hospitals	0
Dorset County Hospital	0
Cheltenham General Hospital	0
Gloucestershire Royal Hospital	0
Royal Gwent Hospital	0

Centres to be open soon

Poole Hospital NHS Foundation Trust
St Helens & Knowsley Teaching Hospitals NHS Trust

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

SAEs & ADVERSE EVENTS OF SPECIAL INTEREST (AESIs):

SAEs and AESIs need to be reported to Cambridge as soon as you know the event has happened. Queries for SAE information and follow-ups will be sent out in the next month – please reply asap as the 200-patient safety report will soon be due.

MANDATORY BLOOD SAMPLES:

Now up and running: blood kits and SOPs have been sent out to all recruiting sites. Please start to collect the mandatory blood samples for all of your ARTEMIS patients recruited to date and going forwards: 2 x 9ml EDTA samples taken once only per patient.

Congratulations to the following sites for collecting mandatory blood samples for all of their patients recruited to date:

- West Middlesex
- Torbay
- Essex
- Bedford

And a good effort from Leeds and Peterborough: only a few more patients left to catch-up!

Any questions, or if you have recruited patients but haven't received any kits, or to request more kits: louise.grybowicz@addenbrookes.nhs.uk or 01223 348447.

FRESH TISSUE:

We need more! Please let us know if you are interested and we will help to sort out the logistics. Please keep approaching your patients if you are able to take part in this important sub-study.

Any problems or questions please feedback to Linda Jones or Susan Ingle at Cambridge: susan.ingle@addenbrookes.nhs.uk or linda.jones@addenbrookes.nhs.uk.

SEQUENTIAL BLOODS:

Please keep approaching patients for this sub-study if you are able to take part. Any problems please feed back to the Edinburgh Endocrine Cancer Team Ria.Kishen@ed.ac.uk or c.drake@ed.ac.uk

OUTSTANDING DATA REQUEST (INCLUDING SURGERY FORMS):

Send all data to Warwick, particularly outstanding Surgery Forms and path reports – requests for pathology blocks and slides cannot be made without this information, and we are currently in the process of requesting blocks and slides for the first 50 trial patients.

SITE SIGNATURE & DELEGATION LOGS:

New staff should be added on a new Site Signature & Delegation Log V2.1 dated 07 December 2009. Please keep your Logs up-to-date and send new additions to Clare at Warwick.

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



Phase III Trial

Warwick Clinical Trials Unit, University of Warwick,
Gibbet Hill Road, Coventry CV4 7AL

Clare Blenkinsop
c.blenkinsop@warwick.ac.uk 024 7615 1072

Pharmacovigilance and Translational Studies

Cambridge Cancer Trials Centre, (S4) Box 279,
Addenbrookes Hospital, Hills Road, Cambridge CB2 0QQ

Louise Grybowicz
louise.grybowicz@addenbrookes.nhs.uk 01223 348447
Anne-Laure Vallier
anne-laure.vallier@addenbrookes.nhs.uk 01223 348086