

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

ARTemis Newsletter Issue 6 March 2011

Welcome to this new edition which will tell you about recruitment, safety data, new CRF and sub-studies.

PATIENT RECRUITMENT: Number of Patients Recruited: 246

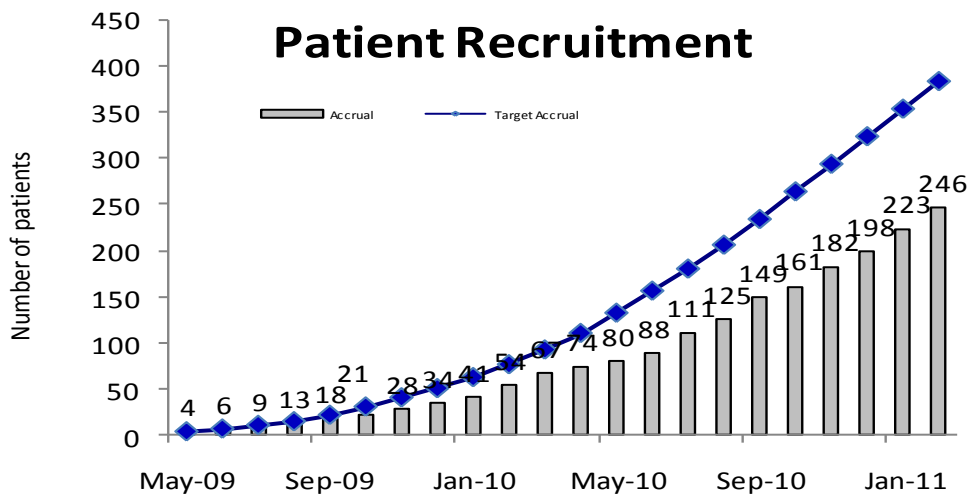
Recruitment has improved: Jan 2011 was the best month so far with 25 patients, but we still need your continuous support to reach a monthly accrual of 30 to 40 patients. Please continue actively screening and randomising more patients into the study and do not hesitate to contact the team if you face any issues.

Note: New sites are welcome to take part.



Well done to Addenbrooke's hospital which has recruited the 200th patient in early January. Congratulations to West Middlesex, Peterborough, Royal Bournemouth and Royal Surrey hospitals, best recruiters so far in 2011.

(as of 28 February 2011)



DEADLINE FOR DATA:

Our first Data Safety and Monitoring Committee will be held at ASCO (3 June, Chicago) where the pre-planned analysis of the safety data for the first 200 patients will be reviewed. The main objective of the committee is to oversee the safety of trial patients and validate the integrity of the trial. **It is therefore essential that you send us your CRFs by the end of April 2011** for inclusion in the DSMC report.

Reminder for SAE reporting

- Please provide SAE reports within the legal 24 hours as required by the MHRA.
- Please continue to report SAEs as per protocol.
- Provide SAE Follow-up reports within the following 2 weeks.

Note: An average of one SAE per patient is expected in ARTemis. Some sites might be under-reporting. Please **ensure that all SAEs are reported to us.**

PLEASE ANSWER DATA QUERIES WITHIN A WEEK

Centres open: sorted by date of activation

| | |
|-----------------------------------|----|
| Addenbrooke's Hospital | 55 |
| Western General Hospital | 25 |
| Charing Cross Hospital | 12 |
| Peterborough District Hospital | 14 |
| West Middlesex Hospital | 15 |
| St James's University Hospital | 10 |
| St Bartholomew's Hospital | 9 |
| Royal Surrey County Hospital | 11 |
| Christie Hospital | 7 |
| Royal Bournemouth Hospital | 9 |
| Torbay District General Hospital | 6 |
| St Mary's Hospital (London) | 4 |
| Essex County Hospital | 3 |
| City Hospital (Sandwell) | 5 |
| UCLH (London) | 5 |
| University Hospital Coventry | 5 |
| New Cross Hospital | 5 |
| Nottingham University Hospital | 7 |
| Newham Hospital | 2 |
| Aberdeen Royal Infirmary | 3 |
| Royal Hampshire County | 3 |
| Maidstone Hospital | 5 |
| Bedford Hospital | 2 |
| Glan Clwyd Hospital | 3 |
| King's College Hospital | 3 |
| Guy's Hospital | 1 |
| Queen's Hospital (Burton) | 3 |
| St John's Hospital | 1 |
| Royal Liverpool University | 1 |
| Southend University Hospital | 4 |
| Macclesfield District Hospital | 2 |
| Southampton General Hospital | 1 |
| Clatterbridge Centre for Oncology | 0 |
| Royal Glamorgan Hospital | 0 |
| Southport Hospital | 0 |
| Freeman Hospital, Newcastle | 0 |
| North Middlesex Hospital | 0 |
| Warrington & Halton Hospitals | 0 |
| Dorset County Hospital | 1 |
| Cheltenham General Hospital | 0 |
| Gloucestershire Royal Hospital | 0 |
| Royal Gwent Hospital | 0 |
| Poole Hospital | 2 |
| St Helens Hospital | 2 |

Centres to be open soon

| |
|--|
| Barking, Havering & Redbridge Hospital |
| Basingstoke & North Hampshire Hospital |
| Blackpool Victoria Hospital |
| Leicester Royal Infirmary |
| Medway Maritime Hospital |
| Prince Charles Hospital |
| Queen Elizabeth Hospital, Birmingham |
| Royal Derby Hospital |
| Royal Free Hospital |
| Sandwell Hospital |
| Stafford Hospital |
| Velindre Hospital |
| Weston Park Hospital, Sheffield |
| Worcestershire Royal Hospital |
| Ysbytu Gwynedd Hospital |

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

NEW CRF BOOKLETS:

The ARTemis team has produced a new CRF booklet (version 4.0) with a built-in writing shield at the back. Included is a new Assessment Schedule, new Tracking Form, and the Withdrawal Form. The re-named Annual Follow-up Forms (forms no longer required for 6 and 18 months post surgery appointments) and the Randomisation Forms have been updated. Please continue to use up your stock of booklets (Version 3.0) in conjunction with Randomisation Forms and Annual Follow-up Forms (Versions 4.0). When these are depleted, request new booklets from Warwick ARTemis Trial Office. Please mark your current Randomisation Form and Follow-up Forms (in booklets Version 3.0) as 'superseded, using Version 4.0' and use photocopies of the new Randomisation and Annual Follow-up Forms (Versions 4.0) kept in the site file.



Please note:

Only PI/Reporting Radiologists are allowed to sign off Radiology CRFs

Only Randomising Clinicians are allowed to sign off Eligibility CRFs (not RNs)

All ineligible (and illegible, so please print your name too!) signatures will be queried

Site Signature & Delegation logs must be kept up-to-date. Use a new log for new staff rather than adding to an existing one, update log when staff leave and copy to Clare at Warwick. Please include your radiologists on the logs for CRF completion responsibility if they are signing the radiology forms. Remember to ask your PI to initial and date amendments to existing staff on the log, and sign and date again at the end of the log.

FRESH TISSUE:

We need more fresh tissue samples! Please let us know if you are interested and we will help to sort out the logistics. Please keep approaching your patients if your site is able to take part in this important sub-study. Any problems or questions please contact linda.jones@addenbrookes.nhs.uk.

MANDATORY BLOODS: Mandatory blood samples reminder – have only received 100 samples out of 246 patients.



We have received only 91 samples out of the 246 patients. If you haven't sent samples in yet, please collect when patients are next in clinic. A list of the samples expected per site is available on request from Louise.

SEQUENTIAL BLOODS:

Please keep approaching patients if your site is taking part in this sub-study. Any problems, please feed back to the Edinburgh Endocrine Cancer Team Ria.Kishen@ed.ac.uk or c.drake@ed.ac.uk. If you do not wish to take part and have received the kits, please contact Clare for return contact details. Also, be aware that the laboratory manual has been updated and supplied to sites as Version 3.0. It has been made clear that it is preferable that samples are fasting & taken before 10am; however this is not compulsory.



OUTSTANDING DATA REQUEST (INCLUDING SURGERY FORMS):

Send all data to Warwick, particularly outstanding On-Study and 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 100 trial patients. Please check that all data fields have been completed before returning the CRFs.

Please be aware that **neo-adjuvant HER-2+** patients can be entered into *PERSEPHONE*.

Herceptin® can be administered either concomitantly or sequentially for 6 or 12 months in conjunction with chemotherapy. For more details, please contact anne-laure.vallier@addenbrookes.nhs.uk



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