



Latest recruitment news

Welcome to the August newsletter!

We are pleased to announce recruitment is improving and we are finally achieving our target accrual of 50 patients a month.

A HUGE thank you to all Sites who are contributing, not just in relation to recruitment, but also for taking the time to screen and approach eligible patients.

Thank You
FOR YOUR HELP

**Current recruitment: 3486 patients
(20.08.14)**

A fantastic 52 patients were randomised in July 2014.
Please help us to keep recruitment up at 50+ patients a month.

Top 20 recruiters (as of 20.08.14)

Addenbrooke's Hospital	83
Peterborough City Hospital	68
Norfolk & Norwich University Hospital	65
Royal Sussex County Hospital	61
Southampton General Hospital	59
St Bartholomew's Hospital	57
Royal Derby Hospital	56
Southend Hospital	55
New Cross Hospital	53
Queen's Hospital (Romford)	51
Maidstone Hospital	51
Royal Liverpool University Hospital	51
Wexham Park Hospital	50
Luton and Dunstable Hospital	49
Charing Cross Hospital	47
Christie Hospital	46
Cumberland Infirmary	46
Eastbourne District General Hospital	45
Royal Hampshire County Hospital	43
Royal Shrewsbury Hospital	42

May 2014 best recruiters

Chesterfield Royal Hospital– entered 3 patients in May, 5 patients so far in 2014, total 26 patients since opening in October 2011.



Photo featuring: Julie Smith, Research Nurse and Emma Hudson, Clinical Trials Administrator. (PI, Dr Omar Din).

Recruitment tips from Julie:

"As a team we find it helpful to have a discussion regarding the trial at the first initial consultation with the oncologist when they talk about adjuvant therapy post surgery, when reassurance is given that this is an important question that needs answering.

It helps to attend MDT meetings and have good communication between all members of the team."

A VERY BIG
THANK YOU
...to Staff at both Sites

Yeovil District General Hospital– entered 3 patients in May, 4 patients so far in 2014, total 27 patients since opening in February 2008.



Photo featuring from left to right:
Dr Urmila Barthakur – Co-Investigator
Dr Geoff Sparrow – PI
Michelle Kotze – Clinical Trials Officer
Kerry Rennie – Research Nurse
(in front) Jess Perry – Oncology Clinical Trial Administrator



Randomisation stratification Trastuzumab timing: Concurrent or Sequential?

Please ensure you have ticked the correct box on the Randomisation form for Trastuzumab timing.

- ◆ Concurrent– patient will be receiving at least one or more chemotherapy cycles with Trastuzumab (even if the last chemotherapy cycle is on the same day as the first Trastuzumab dose)
- ◆ Sequential– patient will be receiving Trastuzumab alone as all chemotherapy was completed before Trastuzumab starts.

Trastuzumab dose details

Please complete details for all doses given before and after randomisation. This also applies to patients who have withdrawn (unless the patient explicitly withdraws consent to follow-up) as we will include all patients randomised in the final analyses.

Trastuzumab loading and re-loading dose

All patients randomised to the PERSEPHONE Trial that are receiving IV Trastuzumab must be given an initial loading dose of 8mg/kg. Subsequent maintenance doses of 6mg/kg must then follow for the remaining cycles as per allocation of treatment arm at randomisation.

Where a patient has had a treatment delay of more than 28 days, a re-loading dose of 8mg/kg must be administered according to the Trastuzumab SmPC. All treatment delays must be documented on the Trastuzumab treatment form.

NB: The current version of Trastuzumab Treatment form is version 3.0 October 2013. Please ensure you are completing this version.

Pregnancy advise

Following review of an SAE involving a foetal death, the DSMC have stressed that when offering the trial to eligible patients it is vital clinical investigators and research nurses ensure diligence in communicating information to patients that pregnancies should be avoided during all Trastuzumab treatment.

Healthcare At Home (H@H) - Update

Following recent communications with H@H we have been informed that the Technical Agreement relating to IV Trastuzumab has currently gone to tender and will be ready for signing early September 2014. H@H will contact all Sites directly in due course.

Screening Log request– reminder

If you haven't sent us your Screening Log yet please do so by **fax: 02476 151 1586** or **e-mail Persephone@warwick.ac.uk**.

The Log should include details of all new patients that were screened, approached and randomised (and declined) to the trial since the last request for Screening Logs was sent.

Translational sub-studies contacts

Please remember your contact for the Trans-PERSEPHONE (Tissue block collection) and Trans-PERSEPHONE—SNPs (blood collection) is Kevin Baker and Anne-Laure Vallier at Cambridge Clinical Trials Unit. Contact details for both are provided below.

Monday 25th– Bank Holiday closure

Please remember to randomise your patient by 5pm Friday 21st August 2014
The PERSEPHONE Trial Office and Randomisation lines will be closed on Bank Holiday Monday
The office and randomisation lines will re-open as usual on Tuesday 22nd 9am till 5pm.

PERSEPHONE team

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