Newsletter June 2017

Optimal Personalised Treatment of early breast cancer using Multi-parameter Analysis

Recruitment update

We've reached triple figures! 104 participants have been randomised.

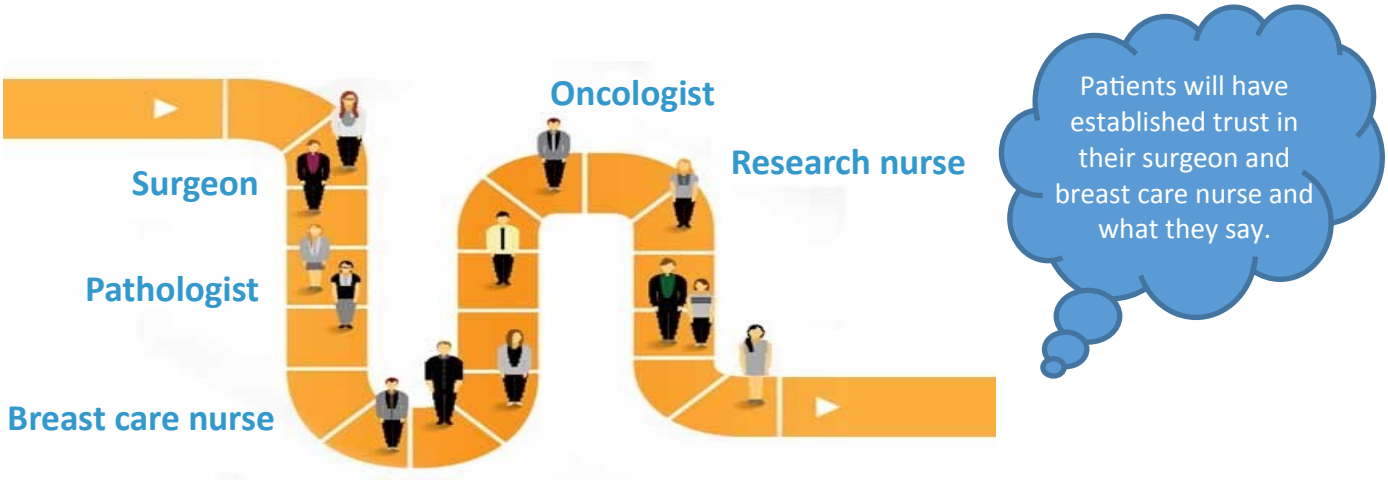
Congratulations to Wrexham Maelor Hospital for recruiting the 100th participant into the OPTIMA trial. In total 30 participants were randomised in June. We now have 60 sites open to recruitment; East Kent University Hospitals NHS Foundation Trust, University Hospital Crosshouse and University Hospital Ayr opened to recruitment this month.

Neoadjuvant therapy excludes patients from OPTIMA

When screening patients for OPTIMA please be aware that patients are not eligible for the study if they have received pre-surgical chemotherapy, endocrine therapy or radiotherapy for breast cancer. Please take care to confirm during the screening process that neoadjuvant treatment has not been given to the patient.

Recruitment tip of the month: present a consistent message to patients

By the time a patient meets with an oncologist or research nurse they may have already developed relationships with their surgeon and breast care nurse. What these staff say about post-surgery treatment, may shape a patient's views about OPTIMA.



At your site, raise the profile of OPTIMA with your surgeons and breast care nurses. Talk with them about their role in the recruitment process. When discussing chemotherapy with a patient, encourage all colleagues to present a consistent message:

The value of chemotherapy is uncertain, it benefits some but not all patients.

Have you got any questions about discussing the OPTIMA study with patients?
Please contact carmel.conefrey@bristol.ac.uk

Recruitment per site

Site *(Information correct as of 30/06/2017)*	Patients randomised
University Hospital Coventry	14
Mount Vernon Hospital	7
University Hospitals of North Midlands	7
Luton and Dunstable University Hospital	6
Addenbrooke's Hospital	5
Russells Hall Hospital, Dudley	5
Wrexham Maelor Hospital, Wrexham	5
Blackpool Victoria Hospital	4
Bristol Haematology & Oncology Centre	4
Royal Alexandra Hospital, Paisley	4
Barnet Hospital	3
Macclesfield District Hospital	3
Peterborough City Hospital	3
Royal Free Hospital	3
Beatson West of Scotland Cancer Centre	2
Hairmyres Hospital	2
Inverclyde Royal Hospital	2
Lister Hospital	2
Nottingham University Hospital	2
Royal Devon and Exeter Hospital	2
Wishaw General Hospital	2
Bedford Hospital	1
Chase Farm Hospital	1
Dumfries and Galloway Royal Infirmary	1
Forth Valley Hospital	1
Glan Clwyd Hospital, Bodelwyddan	1
Northumbria Healthcare NHS FT	1
Pennine Acute Hospitals	1
Queens Hospital, Burton On Trent	1
Royal Shrewsbury Hospital	1
Salisbury District Hospital	1
Sunderland Royal Hospital	1
The Christie	1
University Hospital of North Tees	1
University Hospitals of Morecambe Bay	1
Western General Hospital, Edinburgh	1
York Hospital	1
Ysbyty Gwynedd, Bangor	1

Qualitative Recruitment Study: Audio-Recording

The first audio-recording with a recruiter and patient has been made. If your team has accepted an audio-recorder as part of the Qualitative Recruitment Study, please try to routinely record your appointments where patients are happy to do so. The recordings are treated confidentially.

The recordings provide a valuable insight into recruitment – what works well and the trickier aspects. We'll use this learning to support recruitment across all OPTIMA sites.

Participants who decline to follow trial-allocated treatment

As part of the informed consent process for the study please ensure patients are willing to accept either of the possible treatment outcomes: chemotherapy followed by hormone therapy OR hormone therapy without chemotherapy. However, if a randomised participant later declines to follow their allocated treatment please do not automatically withdraw the participant from the study. If the participant is willing, we would still like them to remain in the study and to collect treatment, patient questionnaire and follow-up data.

Consent Forms

Please **do not** send completed consent forms to the trial office. The original consent form should be filed in your OPTIMA Investigator Site File (section 8.3), a copy given to the patient and a copy filed in the patient's hospital notes.

Contacting the OPTIMA team

Please email us at optima@warwick.ac.uk or contact us on the telephone numbers below.

Amy Campbell, Trial Coordinator, T: 02476 151948

Georgina Dotchin, Trainee Trial Coordinator, T: 02476 151057

Caroline Jevons, Recruitment Facilitator, T: 02476 150990

Kate Packard, Trial Administrator, T: 02476 573423

Carmel Conefrey, Qualitative Recruitment Study, T: 0117 331 4564, E: carmel.conefrey@bristol.ac.uk