POSNOC **NEWSLETTER**

Issue 5 - May 2016



Message From Amit Goyal (Chief Investigator)



The study has successfully completed the in-built feasibility phase and is now in the main recruitment phase. The recruitment period extends to 2018. Study progress was reviewed by NIHR HTA recently and we are greatly encouraged by the favourable monitoring report. Thanks to all your efforts we are close to reaching 500 patients.

With a little extra effort to further boost recruitment we will soon be in a position to answer the question about axillary treatment and spare future women the misery of living with lymphoedema.

The POSNOC Investigators meeting shall be held in Manchester during the Association of Breast Surgery Conference on 16th May, 2016, 18.00-18.45. Hope to see you there!

Amit Goyal

Newly Opened Sites

University Hospital of North Tees-Pud Bhaskar Northampton General Hospital—Craig Knighton

Great Western Hospital - Anushka Chaudhry

Bedford Hospital—Habib Charfare

Worcestershire Acute Hospitals NHS Trust —Steven Thrush

Countess of Chester—Claudia Harding-Mackean

Leighton Hospital—Vanessa Pope

Royal Devon and Exeter Hospital—Douglas Ferguson

Royal Glamorgan — Gary Osborn

Coffs Harbour Health Campus—Karen Briscoe (Australia)

Maeter Hospital - Andrew Spillane (Australia)

Royal Melbourne Hospital - Bruce Mann (Australia)

Site Stories

We recently invited sites to contribute to the newsletter and share their experiences, challenges and methods used to overcome barriers leading to successful recruitment. If your site has a success story you would like to share, please don't hesitate to get in touch!!

Belfast City Hospital



I think the key to successful recruitment in our centre has been active screening for eligible patients at the MDT. When the study opened, the team agreed that we should ensure the study was offered to all eligible patients, and we have been very proactive about making sure that this is the case. Part of that has been making sure we have a high level of awareness of the trial, so that we aren't solely reliant on a single individual being at the MDT for screening – all members of the team (surgeons, oncologists and breast care nurses as well as the clinical research nurses) are involved in identifying eligible patients at the MDT. I think the biggest surprise for us has been that we have seen far fewer than expected potentially eligible patients.

We are also fortunate to have an extremely well-organised clinical research nursing team who pre-empt the patient's arrival at the clinic and ensure that the PIS and DVD are available ahead of the appointment, so that fitting discussion of the trial into a busy results clinic happens smoothly. They also provide telephone follow-up to the women who are offered the trial, to ensure that adequate information is provided and that an opportunity is given to ask questions, and I think that this has really facilitated successful recruitment in our centre.

Stuart McIntosh **Principal Investigator**

United Lincolnshire Hospitals NHS Trust

I believe we have been successful in recruiting patients through detailed communication and explanation of the way the POSNOC trial works. It is about giving factual information in the right manner. Our patients are counselled for the trial by our Consultant Breast Surgeons at the time of the post operative results clinic, meaning that the study is introduced as early as possible thus giving the patient maximal time to consider their participation.

This consultation seems to be the key to our success; clear and concise communication

regarding the patients planned adjuvant systemic therapy and armpit treatment and the risks and benefits of these treatments. The concept of randomisation is also explained at this point. The PIS and DVD are given, and patients are encouraged to consider as a family unit if appropriate. The Research Nurse then telephones the patients a few days to a week later to ascertain the patients thoughts and answer any questions they have. In the whole, our patients have made their own decision as to whether they wish to participate at this time. If they are unsure there is usually plenty of time for further consideration and discussions. Our Consultant Surgeons and Oncologists are happy to arrange extra clinic appointment for trial discussion if necessary.

Amy Kirkby Cancer Research Nurse











Recruitment—(12/05/16)

Total Recruitment	
All Sites	344
Top 10 Recruiting Sites	
Royal Derby Hospital, Derby	26
Wythenshawe Hospital, Manchester	16
Southmead Hospital, Bristol	14
John Radcliffe Hospital, Oxford	13
Royal Bolton Hospital Bolton	12
Belfast City Hospital, Belfast	12
Rotherham Hospital, Rotherham	11
Princess of Wales Hospital, Bridgend	10
Royal Lancaster Infirmary	9
Medway Maritime Hospital	9



Region Totals	
North West	69
South East	48
Scotland	42
Yorkshire & Humber	43
East Midlands	43
Wales	24
South West	22
West Midlands	12
Northern Ireland	12
London	11
East of England	10
North East	7
Australia & New Zealand	1

Randomisation & MACRO Automated Password Reset System Online

We are noticing an increase of users reporting issues with logging into the database systems. We have now introduced an automated reset system if you have forgotten your password. You will now see a forgot my password button when logging in. Please click that and follow the instructions.

Please always remember the following:

- 1. Both systems user login details and passwords are independent from each other. If you change a password on one system it will not update the other database.
- 2. MACRO will ask you to change your password the first time you login. We recommend changing the password for the randomisation system at the same time.
- 3. More than 5 unsuccessful attempts will disable your password in MACRO and you will need to contact us.
- 4. **MACRO** is known to have compatibility issues with older versions of Internet Explorer, sometimes this can be that certain keyboard keys don't respond, which can effect your password entry.

If you suspect this is causing you issues then click on the **Tools** button in Internet Explorer (looks like a cog) then click **Compatibility View Settings,** then enter **Nottingham.ac.uk** under **Add this website:** and click **add.** Then reload the website, if you still experience any issues please get in touch.

DCR (Data Queries) — Closing a Data Query

When closing out a DCR (Red Flag) in Macro, the system requires a "Response" so we are able to see that its been responded to by yourselves. This information is found in the Macro Competition Guidelines, page 17. Please follow these instructions:

- 1. Where the red flag is showing, right mouse click over the red flag a dialog box will show, go to DCR
- 2. Click DCR and select view
- 3. Another box will appear with the data query information (DCR Browser). Anywhere in the white section right mouse click and a dialog box will show
- 4. In the above box please select 'respond to DCR' then record what has been done e.g. Database updated and press OK
- 5. When you have pressed OK the DQ will update, close out of the dialog box (DCR browser) by clicking the little cross in the top right corner of this box.
- 6. You can then leave the page. If the database prompts you to save the page please do so accordingly.

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