

Trial Update

At POSNOC, we have now completed the first year and are into the steep recruitment phase. Our objective is that busy clinicians and MDTs give all eligible patients the opportunity to participate in POSNOC. Quite a challenge!

With the MA20 results highlighting the continued discrepancies in the role of axillary treatment we remain convinced that the only way to get an unbiased view of the risks and benefit of axillary treatment is successful recruitment to POSNOC.

We are very pleased that you as participating sites have stayed with us and remain committed to this aim. The next phase of the study is in your hands, with a real need to get women recruited quickly in order to meet our targets and finish the study in a timely manner!

Amit Goyal—POSNOC Chief Investigator

Australia and New Zealand



Australian and New Zealand investigators are eagerly looking forward to joining the POSNOC trial. Local funding was secured last year, ethics approval has been finalised and agreements will soon be reached to allow the first site (The Royal Melbourne Hospital) to open.

Amit Goyal was an invited speaker at the recent Australia and New Zealand Breast Cancer Trials Group meeting in Perth, where he gave an excellent summary outlining the critical need to complete POSNOC to provide extra information to guide axillary management. We look forward to contributing to this work.

Bruce Mann – Professor of Surgery, Director of Breast Service, Royal Melbourne and Royal Women's Hospital

SHORE-C Update—Communications Workshop

The first Breast Cancer Surgical Trials Communications workshop was held at the Academy of Medical Sciences in London on 7th July. Ten delegates from active POSNOC and LORIS sites attended. The morning session began with everyone sharing their experiences of discussing surgical trials with patients, focussing on the types of patient they found difficult to communicate with, the need to approach patients at a difficult point in their treatment pathway and trial designs that patients find challenging to accept. Delegates were then invited to provide comments on their experiences of watching the LORIS and POSNOC DVDs and any feedback they had received from patients. Selected sections of these DVDs were then played and critiqued by all. Discussion then moved on to factors that can adversely affect or facilitate recruitment such as body language and local site team dynamics "It's fascinating how our own perceptions of the research can 'leak' into the conversation and influence the patients' decisions" (*local principal investigator*).

"This was an interesting day of discussion and practice which gave me further understanding of the need for crystal clear communication when talking to patients about complex (non-)intervention studies" (*local principal investigator*).

After lunch, an actress joined the workshop, firstly as a potential LORIS participant and then as a potential POSNOC participant. She had been briefed to assume some of the personality traits delegates had described as challenging during the morning! Delegates volunteered to discuss the trials with her, answering any difficult questions she raised. The session was interactive, with delegates offering assistance as the discussions unfolded and taking turns to address the patient themselves.

"As a research nurse working on the POSNOC trial, I have found the study day invaluable. I particularly appreciated the interaction, role play and guidance given about difficult conversations. I would recommend the day to anyone facing patients in research"

For details of the next workshop please contact SHORE-C, email: k.monson@sussex.ac.uk

Contact Details

Amit Goyal — Chief Investigator
Amit.Goyal@nhs.net

Contact Details

Shabina Sadiq — Trial Manager
POSNOC@nottingham.ac.uk
(0115 884 4922)

Contact Details

Kathryn Monson — Shore-C
K.Monson@sussex.ac.uk

Recruitment

Total Recruitment to Date

All Sites	173
Top Recruiting Sites	
Royal Derby Hospital	14
Wythenshawe Hospital	11
Belfast City Hospital	10
Southmead Hospital	9
The Royal Bolton Hospital	9
Macclesfield District General	7
North Manchester	6
Rotherham Hospital	6


Latest Document Versions

We have recently sent out to all sites an updated Version Control Log, this lists all the documents which have been approved for use at your site. Please ensure all your documents are up-to-date and that you are using the latest CRF (v2.23) An updated CRF completion guide will follow shortly. We will release the new POSNOC Poster once printing arrangements have been made.

Please check and ensure you have and are using the correct documents:

- Consent v2.0
- Patient Information Sheets v2.0
- POSNOC Protocol v3.0
- GP Letter v1.0
- CRF v2.3

POSNOC Site Update—Regions

Region	Count	Recruitment by Region	Region	Count
Yorkshire and Humber	34		Scotland	16
Bolton NHS Foundation Trust	9		Wishaw General Hospital	4
Rotherham Hospital	6		Western General Hospital	3
Castle Hill Hospital	5		Forth Valley Royal Hospital	2
Bradford Royal infirmary	5		Western Infirmary Glasgow	2
Barnsley General Hospital	4		Royal Alexandra Hospital	2
St James University Hospital	4		University Hospital Crosshouse	1
Weston Park Hospital	1		Ninewells Hospital	1
Doncaster Royal Infirmary	0		Inverclyde Royal Hospital	0
North West	39		New Victoria	1
Wythenshawe Hospital	11		Wales	13
Royal Lancaster Infirmary	5		University Hospital Llandough	5
Macclesfield District General	7		The Princess of Wales Hospital	5
North Manchester General	6		Royal Gwent Hospital	3
Royal Stoke University Hospital	4		Northern Ireland	10
Royal Liverpool Hospital	3		Belfast City Hospital	10
Whiston Hospital	3		South West	11
Cumberland Infirmary	0		Southmead Hospital	9
East Midlands	16		Royal Cornwall Hospital	1
Royal Derby Hospital	14		Yeovil District Hospital	1
Chesterfield Royal	2		West Midlands	7
Leicester Royal Infirmary	0		Queen Elizabeth Medical Centre	2
South East	16		New Cross Hospital	2
John Radcliffe Hospital	5		City Hospital Birmingham	3
Medway Maritime Hospital	4		East of England	5
Darent Valley Hospital	2		Addenbrookes Hospital	4
Maidstone Hospital	2		Norfolk and Norwich Hospitals	1
Conquest Hospital	1		North East	3
Eastbourne District General	1		Newcastle Royal Victoria	3
St Peters Hospital	0		London	3
Wycombe Hospital	1	St Thomas Hospital	2	
		Royal Marsden Hospital	1	

New Staff \ GCP Compliance

All sites must ensure that all new members of staff working on the POSNOC trial are signed onto the delegation log by the PI, ensure that their GCP and signed CV are up-to-date, receive adequate training on the delivery of the trial and are appropriately recorded on the training log. Also please ensure a copy of all these documents are sent to POSNOC@nottingham.ac.uk before they commence trial work.

Please remember GCP compliance must be upheld at all sites and it is ultimately the PI's responsibility to ensure this.