To be printed on local headed paper

POSNOC - A randomised trial of armpit (axilla) treatment for women with early stage breast cancer

POSNOC - POsitive Sentinel NOde: adjuvant therapy alone versus adjuvant therapy plus Clearance or axillary radiotherapy.

Participant Information Sheet - Intra-operative sentinel node assessment

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IRAS Project ID: 137785

You are invited to take part in our research study

- It is important you understand why the research is being done and what it would involve for you if you decide to take part.
- Please take time to read this information. Talk to others if you wish, and ask if you would like more information.
- It is for you to decide if you want to join the study or not. If you agree to take part, you are free to withdraw at any time without giving a reason. If you choose not to take part, your care will continue in the normal way. You will receive the usual care for patients with early stage breast cancer.
- Thank you for reading this information.

Important things that you need to know

- Women with early breast cancer that has spread to the first 1 or 2 lymph glands (sentinel nodes) will receive chemotherapy or endocrine therapy (hormone therapy), or both. Radiotherapy is given to the breast in all women who undergo lumpectomy, and to the chest wall in some who undergo mastectomy. These treatments are called adjuvant therapy treatments - which means they are performed after the initial treatment.
- Currently these women also have treatment to their armpit (axilla). This treatment is to remove all the lymph glands in the armpit and can be performed during the same surgery as their lumpectomy or mastectomy (or as a separate surgery). Treatment to the armpit may also be given via radiotherapy.
- Armpit treatments can have side effects such as long term swelling of the arm, shoulder stiffness, and numbness or pain in the arm or hand.
- Adjuvant therapy treatments are effective treatments and in recent years have advanced: they can reach everywhere and target the cancer anywhere in the body. Previous studies suggest that these treatments are good at treating breast cancer that has spread to the armpit, without having further treatment directly to the armpit.
- We are doing this international study to see if adjuvant therapy treatments are as beneficial as adjuvant therapy treatments plus armpit treatment. If armpit treatments are shown to be of no extra benefit, women could avoid the side effects of armpit treatment. If you take part, you will be followed-up alongside your normal clinic visits: every six months for the first year, and then annually for five years. There are no extra tests.

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How to contact us

If you have any questions about this study, at any time, please contact your local research team at:

[INSERT CONTACT DETAILS HERE]

1. Why we are doing this study?

Each year more than 48,000 women are diagnosed with breast cancer in the UK. Currently women having surgical treatment for their breast cancer also undergo removal of the first one or two lymph glands (sentinel nodes) from the armpit to check if the cancer has spread to the lymph glands in the armpit. This procedure is called sentinel node biopsy.

For about a quarter of women, the breast cancer has spread to the armpit. All of these women will have the cancer in their breast and armpit treated with chemotherapy or hormone therapy, or both. Radiotherapy is given to the breast in all women who undergo lumpectomy, and to the chest wall in some who undergo mastectomy (removal of whole breast). These treatments are called adjuvant therapy treatments.

Currently, these women are offered additional treatment to their armpit. This is either a second operation to remove all the lymph glands in the armpit (node clearance) or radiotherapy to the armpit depending on local hospital practice.

However armpit therapy can have side effects such as long term swelling of the arm, shoulder stiffness, and numbness or pain in the arm or hand. Some women can also develop lymphoedema which is when fluid collects in the arm and doesn't drain in the normal way. These can be life-long side effects.

We now know that the new types of adjuvant therapy treatments are very good at treating breast cancer and at preventing the cancer from coming back. These treatments can reach everywhere and target the cancer anywhere in the body. Evidence from previous research suggests the additional armpit treatment may now no longer be needed. However, this research was not of high enough quality, and the studies were too small to give a clear answer.

We are doing this study to find out whether adjuvant therapy treatments are just as good at treating cancer and preventing it from coming back as the current standard of adjuvant therapy treatments with armpit treatment. If they are just as effective, we could potentially prevent women receiving unnecessary treatment and possible life-long side effects.

To answer this question we need 1,900 women to take part in the POSNOC trial. All women will receive treatment for their breast cancer and will be closely monitored.

2. Why have I been invited to take part?

You are being invited to take part in this study because you have early breast cancer which may have spread to the first one or two lymph glands and your clinical team have decided that you should have adjuvant therapy treatments.

At your hospital, the surgeons find out whether cancer has spread to the lymph glands while you are in the operating

theatre. If you do not have cancer spread to the lymph glands at the time of your surgery you will not be entered into the study.

3. What will I have to do if I take part?

If you decide to take part, you will be asked to sign a consent form before your surgery and participation in the study.

The lab result of your lymph glands (sentinel node biopsy) will be given to your surgeon while you are under the anaesthetic. If it shows cancer has spread to one or two lymph glands you will be entered into the study during the surgery.

Your cancer will be treated with either:

(i) Adjuvant therapy treatments

or

(ii) Adjuvant therapy treatments plus armpit treatment.

The armpit treatment will be surgical removal of the remaining lymph glands in the armpit while you are still in the operating theatre or radiotherapy to the armpit afterwards and shall be decided before your operation.

Which treatment you get is decided by a process called randomisation. Neither you nor your doctor or nurse will be able to choose: a computer programme will allocate you to one or the other group. This may sound strange but randomisation ensures a fair comparison. The computer programme puts equal numbers of patients of different ages and states of health in each group so that at the end of the study we are sure that any differences between women in the two groups are due to whether or not they had armpit treatment, rather than anything else.

You will not need any additional procedures or tests if you take part in the study and you will not have any extra clinic visits. We will do the study follow up within your normal NHS care. You will be monitored in the outpatient clinic six months after you consent to remove the breast cancer, then at one year after surgery, and yearly after that for five years. If for any reason we were unable to follow up with you in clinic we may contact you by telephone to ask about your wellbeing since you joined the study.

We will also ask you to complete a set of three questionnaires when you join the study, and then again at three months, six months, one year, two years and three years (six sets over three years). These ask about your quality of life, your ability to carry out your normal daily activities and any feelings of anxiety you may have. You will complete the first set of questionnaires in the clinic when you join the study, but the others will be sent to your home by researchers from Sussex Health Outcomes Research and Education in Cancer (SHORE-C), at Sussex University.

We will write to your GP to explain that you are taking part in the study. We may contact your GP if we lose contact with you, for instance because you move home, unless you ask us not to.

If you decide to take part in the study, you are free to withdraw at any time, without giving a reason. This will not affect the standard of care you receive and only the data up until the point of withdrawal will be used.

4.Possible disadvantages or risks?

All participants in the trial will have adjuvant therapy treatments and will be monitored regularly in clinic. However, we do not know whether armpit treatment has any effect on the risk of your cancer coming back. That is why we are doing this study. If there are signs that your cancer has come back your doctor will discuss the best course of action based on your treatment to date.

5.Possible benefits?

We cannot promise the study will help you. But information we get from the study will help improve future care for patients with early breast cancer that has spread to the armpit.

6. What happens after the study?

Normal NHS cancer care is that patients are discharged from the hospital clinic after five years. POSNOC participants will be followed up over this time. After the five years your participation in the trial will end but we may use your health records to check your health status in the future. Your care will continue as decided by your clinical team. If the evidence shows that there is an important difference between the two forms of care for women, then we may want to contact you again in the future to find out how you are.

7.How will my data be used?

We will follow ethical and legal practice and all information about you will be handled in confidence.

We will need to use information from you and your medical records for this research project. This information will include your:

- Initials
- Name
- NHS number
- Contact details
- Date of birth

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

8. What are my choices about how my information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Your personal data (address, telephone number) will be kept after the end of the study so that we are able to contact you about the findings of the study (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 5 years. After this time your data will be disposed of securely.

9. Results of the study

Findings from this study will be published in medical journals, presented at medical conferences and made available to patient groups/relevant charities. We will write to you with a summary of the study findings, unless you ask us not to.

10. What if there is a problem?

If you have a concern or questions about any aspect of this study you should ask to speak to the local researchers (their contact details are on the front page of this leaflet).

If you remain unhappy and wish to complain formally, you can do this through your local complaints procedure *[insert name of service and local contact details].*

In the event that something does go wrong and you are harmed during the study, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

11. Tissue samples

The POSNOC researchers are interested in conducting further research studies on tissue samples from your cancer specimen to better understand the nature of cancer and how patients respond to treatment. This is an optional part of this study. You may choose not to donate your tissue and still take part in the POSNOC study.

If you agree to join this optional part of the study the samples collected will be from the cancer that has already been removed by biopsy or surgery. No further surgery or biopsy is needed for this purpose. The samples will be transferred from your hospital to a central tissue bank and stored anonymously.

Before the samples are used in future research, these new studies will first gain ethical approval.

For those patients who experience a recurrence of their cancer or develop cancer in the other breast, we would at that time also ask to collect and store samples of this new tissue. Again, these samples will be collected from cancer removed by biopsy or surgery and no further procedures would be needed.

You will not receive any personal results from the tests done on the tissue samples as part of future research as it is not yet known whether these tests are useful. This research on tissue samples may not directly benefit you but it may help people in the future who have the same type of cancer as you.

12. Who has reviewed the study?

This study has been reviewed and given favourable opinion by East Midlands – Nottingham 2 Research Ethics Committee (REC). The REC looks after the rights, wellbeing and dignity of people invited to take part in research studies. The study has also been reviewed by the University Hospitals of Derby and Burton NHS Foundation Trust, and the National Institute of Health Research Health Technology Assessment Programme (which has funded the study). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

13. Where can I find out more about how my information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- at https://www.uhdb.nhs.uk/ research -how-we-use-your-information
- by asking one of the research team
- by sending an email to posnoc@nottingham.ac.uk

Thank you for reading this leaflet, you will be given a copy of this Participant Information Sheet to keep.

Patient information DVD can be viewed online on YouTube & www.posnoc.co.uk

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