



IRAS project ID: 137785

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

DATA TRANSPARENCY STATEMENT

If you are taking part in the POSNO study, this statement describes how your data is being used and are being stored. We would like to take this opportunity to thank you for your involvement in the study.

The purpose of the POSNO study is to see whether adjuvant therapy treatments are as beneficial as adjuvant therapy treatments plus armpit treatment. It will also consider acceptability to patients and value for money. The results of the study will inform national guidelines about the best way to treat women who have had surgery for breast cancer.

University Hospitals of Derby and Burton NHS Foundation Trust (UHDB) is the Sponsor of this study and the data controller for the research. This means that UHDB is responsible for deciding how and why your personal information is used and for ensuring that it is handled in accordance with data protection laws.

The study is managed by the Nottingham Clinical Trials Unit (NCTU), part of the University of Nottingham, on behalf of UHDB. NCTU supports the management and delivery of the study and processes personal information only on behalf of, and under the instructions of, UHDB. NCTU is not permitted to use your information for its own purposes and acts as the data processor for the study.

Everyone that took part in the POSNO study was asked to sign a Consent Form. As a reminder, you provided signed, written consent for your personal data to be accessed by both the University Hospitals of Derby and Burton NHS Foundation Trust and Nottingham Clinical Trials Unit. Your NHS hospital will collect information from you and your medical records for this research study in accordance with our instructions, and pass this information on to the study team at the Nottingham Clinical Trials Unit.

Your NHS hospital will use your NHS number and contact details to contact you about the POSNO study during the five years you are taking part. They will also use this information to ensure that relevant details about the study are recorded as part of your care and to help monitor the quality of the study.

Individuals from University Hospitals of Derby and Burton NHS Foundation Trust, Nottingham Clinical Trials Unit and regulatory organisations may look at your medical and research records to check the accuracy of the research study.

You can find out more about how we use your information here:

- University Hospitals of Derby and Burton NHS Foundation Trust (Sponsor) <https://www.uhdb.nhs.uk/research-how-we-use-your-information>
- Nottingham Clinical Trials Unit, University of Nottingham <https://www.nctu.ac.uk/about-us/data-protection.aspx>

To conduct this study, NCTU will use information collected from you and relevant information from your medical records on behalf of UHDB. Identifiable information about you will be retained by the Sponsor for at least five years after the completion of the trial.

The POSNO study opened in August 2014 and recruited participants until July 2021. Participants were followed up as part of the main study for five years after joining the trial. After this period, we may continue to collect and link information about your health as part of long-term follow-up. This helps researchers

understand the longer-term effects of treatment and may include securely accessing and linking information from routine healthcare records, such as NHS records, where relevant. This long-term follow-up applies to all participants unless they have withdrawn their consent.

As understanding long-term outcomes is an important part of the research, follow-up may continue for many years and may not have a fixed end date where this is necessary for scientific research.

Information that could identify you will be kept for at least five years after the study has finished, including the long-term follow-up period, in line with regulatory requirements. After this time, information that could identify you may be securely archived or, where possible, changed so that you can no longer be identified. Research data with your name and other direct identifiers removed may continue to be kept and used for research to support the long-term follow-up and the scientific aims of the study.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, including any long-term follow up data collection, we will keep the information about you that we have already obtained.

You can withdraw at any time by contacting the POSNOC study team using the details provided here: <http://www.posnoc.co.uk/contact.aspx>. To safeguard your rights, we will use the minimum personally identifiable information possible. If a participant withdraws, no further data will be collected; however, information already collected may continue to be used to maintain the integrity and reliability of the research.

The POSNOC study will collect information about you, including long-term follow up data, for research purposes from NHS England (formerly known as NHS Digital), Office of National Statistics (ONS) and other relevant bodies to provide information about your health status. NHS England is an organisation that collects health and care data from NHS hospitals in England and Wales.

The study team will provide NHS England with your NHS number, date of birth and unique trial ID number to allow us to link to the data held by NHS England. NHS England will transfer data back to the University of Nottingham and University Hospitals of Derby and Burton NHS Trust regarding any hospital admissions and appointments over the study period, plus information about any further cancer diagnoses and survival.

The data transferred back to the University of Nottingham and University Hospitals of Derby and Burton NHS Trust will be identified by your trial ID number only. Data transfer will be using a secure, encrypted procedure.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the [UK Policy Framework for Health and Social Care Research](#). Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance. Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.