

# ATNEC - Axillary management in T1-3N1M0 breast cancer patients with needle biopsy-proven nodal metastases at presentation after neoadjuvant chemotherapy

<b>Submission date</b> 26/10/2020	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/12/2020	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/06/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-further-treatment-to-the-axilla-after-surgery-to-remove-breast-cancer-atnec>

### Background and study aims

Early-stage breast cancer patients with abnormal-looking axilla lymph glands on an ultrasound scan will have a sample (needle biopsy) of this lymph gland taken. If the sample shows cancer cells are present, patients are often given chemotherapy before surgery (called neoadjuvant chemotherapy) to shrink these cancer cells before their operation. Currently after chemotherapy, all patients undergo breast surgery (lumpectomy or mastectomy) and treatment to their axilla (either removal of all axilla lymph glands or radiotherapy to the axilla). Neoadjuvant chemotherapy results in complete disappearance of cancer in the lymph glands in around 40-70% of patients. For these patients there may be no extra benefit from more treatment to their axilla. Any extra axilla treatment may damage lymphatic drainage from the arm, which could lead to arm swelling (lymphoedema), restricted shoulder movement, pain, numbness and other sensory problems. These side effects make some daily activities difficult for patients, they are distressing and affect their quality of life. They are costly to the NHS in terms of treatments such as physiotherapy and attendance at lymphoedema clinics.

The aim of this study is to find out whether stopping further axilla treatment for patients with no cancer in the lymph glands after chemotherapy is safe, in terms of risk of cancer coming back and fewer lymphoedema cases at 5 years. After neoadjuvant chemotherapy and at the time of breast surgery, patients will undergo removal of at least three lymph glands from the axilla. If there is no cancer in the removed glands, patients will be randomly allocated to receive standard axilla treatment or no further treatment to the axilla.

Results of this study could benefit patients by avoiding unnecessary treatment to the axilla and thus reducing future problems with the arm and shoulder, and possibly improved quality of life and reduced healthcare costs.

## Who can participate?

Patients aged 18 or older with early-stage breast cancer that has spread to the lymph gland in their armpit, who will receive (or has received) standard neoadjuvant chemotherapy

## What does the study involve?

Eligibility for the randomised portion of the trial will be assessed following completion of neoadjuvant chemotherapy and surgery. The patient's clinician will assess how well their cancer has responded to treatment. If following these assessments, there is no remaining sign of cancer in the patient's armpit lymph glands, then they will be deemed eligible to take part in the randomised stage of the study. Patients eligible for the study will receive either:

1. No further treatment to your armpit, following neoadjuvant chemotherapy and breast surgery, or
2. Further treatment to your armpit, following neoadjuvant chemotherapy and breast surgery

Which treatment patients receive (option 1 or option 2) is decided by a process called randomisation. Neither patients nor their doctor will be able to choose which group is assigned; treatment allocation will be decided randomly by a computer.

If a patient is allocated further treatment to their armpit (option 2), they, together with their doctor, can choose either surgery to remove all remaining lymph glands in the armpit or radiotherapy to the armpit area.

All participants, regardless of which group they are allocated to, will still receive other standard treatment for their breast cancer, such as radiotherapy to the breast and chest wall, and hormone therapy. This treatment will be given as indicated, upon the advice of the clinical team. Patients who are eligible for the study will also be asked to complete a short questionnaire booklet; there will be five further questionnaire booklets to complete over the course of the study. The researchers will use the responses to assess how patients are feeling with respect to their treatment. Each questionnaire should take approximately 20 minutes to complete.

## What are the possible benefits and risks of participating?

The researchers cannot promise that this study will help participants, but it may help patients in the future. Findings from this study will also help inform the future care of patients with early breast cancer that has spread to the armpit. The researchers do not know whether removing further armpit treatment, if there are no signs of cancer left in patients' lymph glands, will have an impact on the risk of their cancer returning – that is why they are doing the study. All participants will be closely monitored by their clinical care team, and if there is any sign of cancer recurrence, their doctor will discuss the best course of action.

X-rays, nuclear medicine imaging and radiotherapy, where appropriate, are part of patients' routine care. If patients take part in this study, they will not undergo any additional imaging or radiotherapy. These procedures use ionising radiation to form images of the body and/or provide treatment and/or provide doctors with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. Patients' doctors will discuss other possible side-effects of radiotherapy with them. The chances of these things happening to patients are the same whether they take part in this study or not.

Participants will be asked to complete questionnaires which will take some of their time (about 20 minutes per questionnaire). As the questionnaires form a key part of our data collection for the study, it is important for participants to consider whether they will have the time to complete these fully. Participants will be issued with one questionnaire booklet at trial entry and then five further questionnaires at the following time points: 1 year, 2 years, 3 years, 4 years and 5 years.

## Where is the study run from?

University Hospitals of Derby and Burton NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?  
March 2020 to March 2030

Who is funding the study?  
National Institute for Health Research (NIHR) (UK)

Who is the main contact?  
ATNEC Trial Management team  
ATNEC@warwick.ac.uk

## Contact information

**Type(s)**  
Scientific

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**Type(s)**  
Public

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ATNEC@warwick.ac.uk

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

## **Integrated Research Application System (IRAS)**

280105

## **ClinicalTrials.gov (NCT)**

NCT04109079

## **Protocol serial number**

CPMS 46520, IRAS 280105

# **Study information**

## **Scientific Title**

ATNEC - Axillary management in T1-3N1M0 breast cancer patients with needle biopsy-proven nodal metastases at presentation after neoadjuvant chemotherapy

## **Acronym**

ATNEC

## **Study objectives**

Omitting further axillary treatment (ALND and ART) for patients with early-stage breast cancer and axillary nodal metastases on needle biopsy, who after NACT have no residual cancer in the lymph nodes on sentinel node biopsy, will be non-inferior to axillary treatment in terms of disease-free survival (DFS) and will result in a reduced risk of lymphoedema at 5 years.

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

approved 22/10/2020, Yorkshire & The Humber – Bradford Leeds Research Ethics Committee (Newcastle Blood Donor Centre, Holland Drive, HRA Newcastle, Newcastle, NE2 4NQ, United Kingdom; +44 (0)207 104 8083, +44 (0)207 104 8088, +44 (0)207 104 8018; bradfordleeds.rec@hra.nhs.uk), ref: 20/YH/0232

## **Study design**

Randomized; Both; Design type: Treatment, Process of Care, Surgery, Other, Health Economic

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Breast cancer

## **Interventions**

Current interventions as of 19/07/2023:

ATNEC is a multi-centre, randomised clinical trial with a non-inferiority endpoint and a pragmatic design. ATNEC will be conducted in patients with early-stage, node-positive breast cancer,

whose usual treatment pathway would be neoadjuvant chemotherapy followed by breast surgery and further treatment to the armpit (lymph node clearance or radiotherapy to the armpit). Patients who have no residual cancer in the lymph glands after chemotherapy will be randomised to either have standard armpit treatment or no further treatment to the armpit.

An integrated feasibility study, with embedded qualitative research, will assess the willingness of clinicians and patients to participate in the ATNEC trial.

#### Pre-Randomisation:

To be eligible, a patient must be diagnosed with early-stage, confirmed node-positive breast cancer on needle biopsy, and planned to receive chemotherapy first (neoadjuvant chemotherapy) prior to surgery. The patient's primary tumour must have been evaluated for receptor status. Patients can be either female or male, and must be aged 18 years or older.

Patients who are confirmed to be eligible will be invited to take part in the study and if, following review of the patient information sheet, they decide to participate, written informed consent will be obtained.

Once a patient has consented to participate, the site team will be able to register them to the study via the ATNEC online registration portal. The patient will be assigned a unique trial number, which will be used to identify them throughout the study.

It is recommended that the patient's clinical team will mark the abnormal armpit lymph gland – this could be done either by using a clip, carbon dye or by inserting a magnetic seed as per local practice. Patients will then continue to receive neo-adjuvant chemotherapy, as per standard practice.

Following the completion of their chemotherapy, patients will undergo imaging assessment of the lymph glands to check for abnormal-looking lymph glands. If the armpit lymph glands are found to still contain residual cancer cells, the patient will not be eligible for randomisation and will continue with treatment for their cancer, per standard practice. If the ultrasound shows no confirmed evidence of residual cancer, then the patient will proceed to breast surgery (either lumpectomy to remove the lump, or mastectomy to remove the breast). During their operation, a procedure called a sentinel lymph node biopsy will also be performed; this will involve the removal of at least three lymph glands (including the original marked gland). The removed glands will be tested to provide definitive confirmation that the patient has no remaining cancer in their armpit glands. At this point, the patient will be deemed eligible for randomisation.

Patients who are deemed eligible, but have not previously been registered, can also enter the trial at this point. Patients who are willing to participate will be consented after their surgery, registration and randomisation will take place as one process.

#### Randomisation/Baseline:

Prior to randomisation, patients will be issued with a baseline questionnaire booklet containing the following questionnaires: the lymphoedema and breast cancer questionnaire (LBCQ), a shortened version of the Disability of the Arm, Shoulder and Hand (QuickDASH) questionnaire, a health utilisation questionnaire, and the EQ-5D-5L questionnaire which captures information about a patient's overall health state.

Eligible patients, with continuing consent, will be randomised to the study via the online ATNEC randomisation portal. Patients will be randomised to receive either standard treatment to the armpit (lymph node clearance or radiotherapy to the armpit) or no further armpit treatment.

#### Follow-Up:

Patients are required to complete five further questionnaire booklets: at 1 year, 2 years, 3 years, 4 years and 5 years post-randomisation. These questionnaire booklets will be posted directly to patients by Warwick Clinical Trials Unit, to complete at home. Posted questionnaires will include a pre-paid return envelope, so completed questionnaires can be returned to the Warwick Clinical Trials Unit.

Beyond the first year, sites will be asked to follow-up patients annually for at least 5 years. Follow-up can be by capturing information from hospital records or by telephone if the treating site has discharged the patient from clinical follow-up. After 5 years, follow-up information will be sought from NHS Digital health records, so long as the patient has given their consent for this.

#### Radiotherapy Quality Assurance Component:

The ATNEC trial will have an embedded radiotherapy quality assurance programme, coordinated by the National Radiotherapy Quality Assurance (RTTQA) group. Sites will be required to adhere to the specific radiotherapy planning and delivery guidelines, developed by the RTTQA team.

#### Qualitative Sub-Study:

Qualitative research has been embedded within the recruitment phase to identify and investigate recruitment issues and develop effective and realistic strategies to ensure the success of the trial. Participation in any aspect of the qualitative sub-study is optional.

Patients who appear eligible for ATNEC will be asked for their permission to audio-record their conversations with their doctor up until the point that they make their decision on whether or not to participate. Prior to any commencement of recording, patients will be given a brief patient information sheet explaining the qualitative sub-study. Patients will be given sufficient time to review this and ask any questions. If patients agree to be recorded, they will be asked to sign a consent form, providing permission for the audio-recordings of their consultations.

In addition, patients who were invited to take part in ATNEC (including those who declined to take part) may be invited for interview at a later date to discuss the reasons why they may, or may not, have chosen to take part in the trial. A separate patient information sheet will be provided for this purpose and, should the patient be happy to be interviewed, written informed consent will be obtained. Patients will be asked for their permission to have their interview audio-recorded. This permission is covered in the above-mentioned patient information sheet and informed consent form.

It will be made explicitly clear to patients, at the time of their consultation, or following the informed consent process for the trial, that their participation in the qualitative sub-study is completely optional. The decision of patients who decline to take part will be completely respected, and their medical care will not be affected in any way.

Researchers who are involved in the ATNEC trial consent process (i.e clinicians and research nurses) will also be invited for an interview. Research staff will also be provided with an information sheet and their informed consent will be required prior to any audio-recording of patient consultations and/or interviews.

An overall plan for the qualitative sub-study, including timelines for interviews, is attached to this application.

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## Previous interventions:

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Following the completion of their chemotherapy, patients will undergo an ultrasound scan of the lymph glands to check for abnormal-looking lymph glands and if needed needle biopsy. If the armpit lymph glands are found to still contain residual cancer cells, the patient will not be eligible for randomisation and will continue with treatment for their cancer, per standard practice. If the ultrasound shows no confirmed evidence of residual cancer, then the patient will proceed to breast surgery (either lumpectomy to remove the lump, or mastectomy to remove the breast). During their operation, a procedure called a sentinel lymph node biopsy will also be performed; this will involve the removal of at least three lymph glands (including the original marked gland). The removed glands will be tested to provide definitive confirmation that the patient has no remaining cancer in their armpit glands. At this point, the patient will be deemed eligible for randomisation.

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An overall plan for the qualitative sub-study, including timelines for interviews, is attached to this application.

## **Intervention Type**

Mixed

## **Primary outcome(s)**

Co-primary outcomes, collected annually for 5 years:

1. Disease-Free Survival (DFS); defined and calculated as the time from randomisation until the date of the first event of either a loco-regional invasive breast cancer relapse, distant relapse, ipsilateral or contralateral new invasive primary breast cancer or death by any cause or the censor date
2. Lymphoedema: self-reported based on two items from the validated Lymphoedema and Breast Cancer Questionnaire (LBCQ) (arm "swelling now" and arm "heaviness in the past year"). Lymphoedema will be defined as 'yes' to both questions at 5 years.

## **Key secondary outcome(s)**

Collected annually for 5 years:

1. Arm function assessed using the shortened version of the Disability of the Arm, Shoulder and Hand (DASH), the 11-item QuickDASH questionnaire, over 5 years
2. Pain intensity and characteristics measured using questions from the Douleur Neuropathique (DN4) and Pain Numeric Rating Scale (NRS) and will relate to the areas affected by surgery and cancer treatment, over 5 years
3. Axillary recurrence-free interval, calculated from the date of randomisation to the date of axillary recurrence or the censor date. Axillary recurrence is defined as pathologically (cytology or biopsy) and/or radiologically confirmed recurrence in lymph nodes draining the primary tumour site. The date of axillary recurrence is the date on which imaging or pathology report (whichever comes first) confirms axillary recurrence. Axillary recurrence will be compared between the two allocated groups over 5 years
4. Overall survival; calculated as the time from randomisation until the date of death by any cause or the censor date. Overall survival will be compared between the two allocated groups over 5 years
5. Local (breast or chest wall) recurrence is defined as pathologically (cytology or biopsy) and/or radiologically confirmed recurrence after mastectomy in the skin or soft tissue of the chest wall within the anatomical area bounded by the mid-sternal line, the clavicle, the posterior axillary line and the costal margin or any type of breast carcinoma in the breast after conservation therapy. The date of local recurrence is the date on which the imaging or pathology report (whichever comes first) confirms local recurrence. Local recurrence will be compared between the two allocated groups over 5 years
6. Regional (nodal) recurrence is defined as pathologically (cytology or biopsy) and/or radiologically confirmed recurrent tumour in the lymph nodes in the ipsilateral axilla, infraclavicular, supraclavicular fossa, interpectoral area or ipsilateral internal mammary chain. The date of regional recurrence is the date on which the imaging or pathology report (whichever comes first) confirms local recurrence. Regional (nodal) recurrence will be compared between the two allocated groups over 5 years
7. Distant metastasis is defined as confirmed metastasis (positive pathology and/or definitive

evidence on imaging) in all other sites of recurrence and may include those classified as: soft-tissue category, visceral category, central nervous system and skeletal spread. The date of distant metastasis is the date on which the imaging or pathology report (whichever comes first) confirms metastasis. Distant metastases will be compared between the two allocated groups over 5 years.

8. Contralateral breast cancer is defined as a new primary malignancy in the opposite breast unless obviously contiguous with recurrent chest wall disease or proven on cytology/biopsy to be of metastatic origin. Contralateral breast cancers will be compared between the two allocated groups over 5 years.

9. Non-breast cancer is defined as any new non-breast primary malignancy, except for basal or squamous cell cancer of the skin, in situ carcinoma of the cervix, or in situ or stage 1 melanoma. New breast cancers will be compared between the two allocated groups over 5 years.

10. Economic evaluation (data to be collected annually, over 5 years, through annual follow-up and patient questionnaires):

10.1. Costs to the NHS and participants will be compared between the two allocated groups over 5 years

10.2. Quality-adjusted life years (QALYs) will be compared between the two groups over 5 years. QALYs based on responses to the EQ-5D-5L administered at baseline, 12, 24, 36, 48, and 60 months post-randomisation

10.3. Incremental cost per disease-free interval over 5 years

10.4. Incremental cost per lymphoedema avoided over 5 years

10.5. Incremental cost per QALY gained over 5 years

10.6. Incremental cost per QALY over the estimated lifetime of a participant with early-stage breast cancer

## **Completion date**

01/03/2030

## **Eligibility**

### **Key inclusion criteria**

Current inclusion criteria as of 05/02/2024:

1. Age  $\geq 18$  years
2. Male or female
3. cT1-3N1M0 breast cancer at diagnosis (prior to NACT) as per AJCC 8th edition
- 3.2 Patients with occult primary invasive breast cancer (no identifiable invasive cancer in the breast) with FNA or core biopsy provide nodal metastases are also eligible for the study.
4. FNA or core biopsy confirmed axillary nodal metastases at presentation
5. Oestrogen receptor and HER2 status evaluated on primary tumour
6. Received standard NACT as per local guidelines (Patients undergoing neoadjuvant endocrine therapy as part of another clinical trial are eligible)
7. Imaging of the axilla, as required, to assess response to NACT (per local guidelines)
8. Undergo a dual tracer sentinel node biopsy (SNB) after NACT with at least 3 nodes removed in total (sentinel nodes and marked node).
- 8.1 If a single tracer SNB is performed: the patient is eligible only if the involved node is marked before or during NACT, and at least 3 nodes (including the marked node) are removed during sentinel node biopsy.
- 8.2 If the node is not marked, or marked node is not removed: the patient is eligible only if the histology report shows evidence of downstaging with complete pathological response e.g. fibrosis or scarring in at least one node and at least 3 nodes removed.

8.3 If fewer than 3 nodes are found on histology: the patient is eligible only if BOTH points a) and b), below, are met:

a) involved node was marked and removed during SNB; and

b) removed marked node shows evidence of downstaging on histology e.g. fibrosis or scarring.

8.4 If the sentinel node(s) cannot be localised on SNB: axillary node sampling should be performed, the patient will be eligible if at least 3 nodes are removed (including the marked node).

9. No evidence of nodal metastases post NACT (isolated tumour cells, micro or macrometastasis)

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Previous inclusion criteria as of 19/07/2023 to 05/02/2024:

1. Age  $\geq 18$  years

2. Male or female

3. cT1-3N1M0 breast cancer at diagnosis (prior to NACT) as per AJCC 8th edition

4. FNA or core biopsy confirmed axillary nodal metastases at presentation

5. Oestrogen receptor, progesterone receptor and HER2 status evaluated on primary tumour

6. Received standard NACT as per local guidelines (Patients undergoing neoadjuvant endocrine therapy as part of another clinical trial are eligible)

7. Imaging of the axilla to assess response to NACT (as per local guidelines)

8. Undergo dual tracer sentinel node biopsy after NACT and at least 3 nodes removed (sentinel nodes and marked node).

8.1 If a single tracer is used, the patient will be eligible if the involved node is marked before or during NACT, and the marked node and at least 3 nodes (including the marked node) are removed during sentinel node biopsy.

8.2 If axillary node sampling is performed following failed localisation of sentinel nodes, patient will be eligible if at least three nodes removed (including the marked node).

8.3 If node is not marked, or marked node is not removed, the patient will be eligible if the histology report shows evidence of downstaging with complete pathological response e.g. fibrosis or scarring in at least one node and at least 3 nodes removed.

8.4 If fewer than 3 nodes are found on histology, the patient is eligible if: a) involved node was marked and removed during SNB; and b) removed marked node shows evidence of downstaging on histology e.g. fibrosis or scarring.

9. No evidence of nodal metastases post NACT (isolated tumour cells, micro or macrometastasis)

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Previous inclusion criteria:

1. Age  $\geq 18$  years

2. Male or female

3. T1-3N1M0 breast cancer at diagnosis (prior to NACT)

4. FNA or core biopsy confirmed axillary nodal metastases at presentation

5. Oestrogen receptor, progesterone receptor and HER2 status evaluated on primary tumour

6. Received standard NACT as per local guidelines (Patients undergoing neoadjuvant endocrine therapy as part of another clinical trial are eligible)

7. Ultrasound of the axilla at completion of NACT

8. Undergo dual tracer sentinel node biopsy after NACT and at least 3 nodes removed (sentinel nodes and marked node). If axillary node sampling is performed following failed localisation of

sentinel nodes, patient will be eligible if at least three nodes removed (including the marked node)

9. No evidence of nodal metastases post NACT (isolated tumour cells, micro or macrometastasis)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Current exclusion criteria as of 19/07/2023:

1. Bilateral synchronous invasive breast cancer
2. Sentinel node biopsy prior to NACT
3. Previous axillary surgery on the same body side as the scheduled targeted sampling
4. Any previous cancer within 5 years or concomitant malignancy except:
  - 4.1. Basal or squamous cell carcinoma of the skin
  - 4.2. In situ carcinoma of the cervix
  - 4.3. In situ melanoma
  - 4.4. Contra- or ipsilateral in situ breast cancer

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Previous exclusion criteria:

1. Bilateral invasive breast cancer
2. Sentinel node biopsy prior to NACT
3. Marked node not removed except where the node/s removed show evidence of down-staging with complete pathological response e.g. fibrosis or scarring
4. Previous axillary surgery on the same body side as the scheduled targeted sampling
5. Any previous cancer within 5 years or concomitant malignancy except:
  - 5.1. Basal or squamous cell carcinoma of the skin
  - 5.2. In situ carcinoma of the cervix
  - 5.3. In situ melanoma
  - 5.4. Contra- or ipsilateral in situ breast cancer

**Date of first enrolment**

21/12/2020

**Date of final enrolment**

01/03/2026

# Locations

## Countries of recruitment

United Kingdom

England

Northern Ireland

Scotland

Wales

Isle of Man

## Study participating centre

### **NHS Grampian**

Summerfield House

2 Eday Road

ABERDEEN

United Kingdom

AB15 6RE

## Study participating centre

### **CAMBRIDGE UNIVERSITY HOSPITALS NHS FOUNDATION TRUST**

ADDENBROOKES HOSPITAL

HILLS ROAD

CAMBRIDGE

United Kingdom

CB2 0QQ

## Study participating centre

### **FRIMLEY HEALTH NHS FOUNDATION TRUST**

PORTSMOUTH ROAD

FRIMLEY

CAMBERLEY

United Kingdom

GU16 7UJ

## Study participating centre

### **NHS Greater Glasgow and Clyde**

J B Russell House

Gartnavel Royal Hospital

1055 Great Western Road  
Glasgow  
United Kingdom  
G12 0XH

**Study participating centre**  
**NHS Forth Valley**  
33 Spittal Street  
Stirling  
United Kingdom  
FK8 1DX

**Study participating centre**  
**NHS Ayrshire and Arran**  
PO Box 13, Boswell House  
10 Arthur Street  
AYR  
United Kingdom  
KA7 1QJ

**Study participating centre**  
**Belfast Health & Social Care Trust**  
Trust Headquarters  
A Floor - Belfast City Hospital  
Lisburn Road  
Belfast  
United Kingdom  
BT9 7AB

**Study participating centre**  
**NHS Borders**  
Newstead  
MELROSE  
United Kingdom  
TD6 9DB

**Study participating centre**  
**NORTH BRISTOL NHS TRUST**  
SOUTHMEAD HOSPITAL  
SOUTHMEAD ROAD  
WESTBURY-ON-TRYM

BRISTOL  
United Kingdom  
BS10 5NB

**Study participating centre**

**CHELSEA AND WESTMINSTER HOSPITAL NHS FOUNDATION TRUST**  
CHELSEA & WESTMINSTER HOSPITAL  
369 FULHAM ROAD  
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**Liverpool University Hospitals NHS Foundation Trust**  
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FREEMAN HOSPITAL  
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INFIRMARY SQUARE  
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CH49 5PE

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**Countess of Chester Hospital NHS Foundation Trust**  
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**James Paget University Hospitals NHS Foundation Trust**

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Denmark Hill  
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**Study participating centre**  
**Milton Keynes University Hospital NHS Foundation Trust**

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**The Royal Wolverhampton NHS Trust**  
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WV10 0QP

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Hayfield House  
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**The Shrewsbury and Telford Hospital NHS Trust**  
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SY3 8XQ

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St. James's University Hospital  
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LS9 7TF

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**Bradford Teaching Hospitals NHS Foundation Trust**  
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**Tameside and Glossop Integrated Care NHS Foundation Trust**  
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**Study participating centre**  
**The Clatterbridge Cancer Centre NHS Foundation Trust**  
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**Buckinghamshire Healthcare NHS Trust**  
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**Study participating centre**  
**York and Scarborough Teaching Hospitals NHS Foundation Trust**  
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**Study participating centre**  
**Victoria Hospital (blackpool)**  
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United Kingdom  
FY3 8NR

**Study participating centre**  
**Croydon University Hospital**  
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CR7 7YE

**Study participating centre**  
**Lister Hospital**  
Coreys Mill Lane  
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SG1 4AB

**Study participating centre**  
**Ipswich Hospital**  
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United Kingdom  
IP4 5PD

**Study participating centre**  
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SL4 3DP

**Study participating centre**  
**University Hospital Galway**  
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H91 YR71

**Study participating centre**  
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**Study participating centre**  
**Harrogate District Hospital**  
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**Study participating centre**  
**Royal Preston Hospital**  
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PR2 9HT

**Study participating centre**  
**North Tyneside General Hospital**  
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United Kingdom  
NE29 8NH

**Study participating centre**  
**Queen Alexandra Hospital**  
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**Study participating centre**  
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**Study participating centre**  
**Singleton Hospital**  
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**Study participating centre**  
**Russells Hall Hospital**  
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DY1 2HQ

**Study participating centre**  
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**Organisation**

University Hospitals of Derby and Burton NHS Foundation Trust

## Funder(s)

**Funder type**

Government

**Funder Name**

National Institute for Health Research; Grant Codes: NIHR128311

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request. Participant data is stored on a secure server at WCTU where each participant has been assigned a de-identified trial number. Any requests for access to the trial data should be sent to the CI who will inform the data custodians and agreement will be made through the data access committee which will comprise of the principal investigators from the trial management group. For each data sharing request, it is essential that a proforma is completed which will describe the purpose, scope, data items requested, analysis plan and acknowledgment of the trial management team. Requestors who are granted access to the data will be required to complete a data-sharing agreement which will be signed by the requester, sponsor and principal investigator(s). The researchers anticipate that data sharing will be possible after the publication of the primary endpoint of the trial.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes