

A study to find out if early microsurgery to repair damaged lymph vessels can reduce arm swelling after lymph node removal surgery for cancer treatment

Submission date 07/09/2026	Recruitment status Recruiting	☐ Prospectively registered ☐ Protocol
Registration date 13/10/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 13/10/2026	Condition category Cancer	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Surgery for cancer sometimes requires removal of the lymph nodes in the armpit, known as axillary lymph node clearance (ALNC). While this is often necessary for cancer treatment, it carries a risk of causing lymphoedema, a long-term condition that results in painful and disabling swelling of the arm. Lymphoedema can have a major impact on quality of life and currently there are no proven ways of preventing it.

This study is testing whether it is possible to introduce a new surgical technique, called immediate lymphatic reconstruction (ILR), alongside standard cancer surgery. ILR involves reconnecting small lymphatic vessels to tiny veins in the armpit during the operation. This is done using microsurgery and adds around 60 minutes to the procedure. The aim is to restore lymphatic drainage and reduce the risk of developing lymphoedema in the future.

Who can participate?

Patients aged 18 years and over with breast cancer or skin cancer of the trunk who need ALNC

What does the study involve?

Participants will be randomly allocated by computer to one of two groups. One group will receive standard surgery (ALNC alone), while the other group will receive ALNC with ILR. All patients will be followed for up to 2 years. At each follow-up, doctors and nurses will assess the arms for swelling, carry out simple tests such as arm measurements and bioimpedance (a painless electrical measurement), and ask participants to complete questionnaires about wellbeing and quality of life. In some centres, an additional test called indocyanine green (ICG) lymphography may also be used.

What are the possible benefits and risks of participating?

The main purpose of this feasibility study is to test whether this type of trial is practical and to gather early safety data. If successful, the results will inform the design of a larger trial to properly test whether ILR prevents lymphoedema.

Where is the study run from?
The Royal Free Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2026 to September 2029

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

Who is the main contact?
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Contact information

Type(s)

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Additional identifiers

Integrated Research Application System (IRAS)
375171

Central Portfolio Management System (CPMS)
58106

Study information

Scientific Title

A feasibility multicentre randomised controlled trial on microsurgical immediate lymphatic reconstruction to reduce risk of lymphoedema

Acronym

CRYPTIC

Study objectives

This study aims to evaluate the feasibility of performing a multicentre randomized controlled trial (RCT) on immediate lymphatic reconstruction in prevention of lymphoedema.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 07/09/2026, West of Scotland REC 4 (Research Ethics – Room 29 2nd Floor Administration Building Gartnavel Royal Hospital 1055 Great Western Road, Glasgow, G12 0XH, United Kingdom; +44 (0)141 314 4485/0213; ggc.wosrec4@nhs.scot), ref: 26/WS/0121

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Active

Assignment

Parallel

Purpose

Prevention, Treatment

Study type(s)

Health condition(s) or problem(s) studied

Patients with cancer requiring axillary lymph node clearance (ALNC) as part of their planned surgical treatment

Interventions

Randomisation will be performed on a 1:1 basis (ILR versus non-ILR (control)). Stratification by site will be applied to balance recruitment across the recruiting NHS hospitals. Participants will be deemed enrolled into the study once they have been randomised to either of the study arms. The assessor will be blinded to the allocation.

The control group undergoes axillary lymph node clearance (ALNC) for breast cancer or skin cancer of the trunk.

The intervention group undergoes ALNC and immediate lymphatic reconstruction.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Recruitment rate measured using the number of patients at 18 months
2. Rate of withdrawal from the study measured using the number of patients at 18 months

Key secondary outcome(s)

1. Proportion of patients developing lymphoedema measured using limb circumference measurements and bioimpedance at up to 24 months
2. Health-related quality of life measured using the Lymphoedema Quality of Life Tool (LYMQoL), the Lymphoedema Life Impact Scale (LLIS) and EQ-5D-5L questionnaires at 1 month and 6 monthly up to 24 months
3. Postoperative complications and adverse events measured using early and late postoperative complications at 1 month and 6 monthly up to 24 months

Completion date

30/09/2029

Eligibility

Key inclusion criteria

1. Adults ≥ 18 years old
2. Diagnosis of breast cancer or skin cancer of the trunk requiring ALNC (with or without neoadjuvant or adjuvant systemic treatment)
3. Patient understands and is willing to consent, can comply with follow-up regime and able to respond to the questionnaires

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

99 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Skin cancer of the ipsilateral upper limb requiring surgical excision
2. Fungating axillary lymph node disease requiring soft tissue reconstruction
3. Inflammatory breast cancer
4. Previous history of upper limb cancer or lymphoedema
5. Prior ipsilateral axillary radiation
6. High risk for general anaesthesia (GA) or not fit for surgery (ASA classification >4)

Date of first enrolment

01/10/2026

Date of final enrolment

31/03/2028

Locations

Countries of recruitment

United Kingdom

England

Wales

Study participating centre

Royal Free London NHS Foundation Trust

Royal Free Hospital

Pond Street

London

England

NW3 2QG

Study participating centre

Charing Cross Hospital

Fulham Palace Road

London

England

W6 8RF

Study participating centre

University College London Hospitals NHS Foundation Trust
250 Euston Road
London
England
NW1 2PG

Study participating centre

The Welsh Centre for Burns and Plastic Surgery
Swansea Bay University Health Board
Heol Maes Eglwys
Morriston
Wales
SA6 6NL

Sponsor information

Organisation

The Royal Free Hospital

ROR

<https://ror.org/01ge67z96>

Funder(s)

Funder type**Funder Name**

National Institute for Health and Care Research

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

IPD sharing plan summary

Not expected to be made available