

Comparison of outcomes on breast reconstruction using two tissue spreading techniques during mastectomy procedure

Submission date 28/02/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 07/03/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/01/2026	Condition category Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The vital component of mastectomy and immediate breast reconstruction is the viability of the preserved skin envelope (with a healthy blood supply) once the underlying breast tissue is excised. Any trauma and compromise of skin vascularity can lead to complications such as infection, skin necrosis and reconstruction failure.

To reduce complications, different interventional methods in mastectomy and immediate breast reconstruction have been tried to prevent post-surgery infections, but none have been widely adopted.

Using a gentle technique to lift the soft tissue could decrease post-surgery infection and reduce patient re-admission and re-operation. To enable a clear view of the operative field during surgery, surgical tools called retractors are used to forcefully lift tissue to allow access for the surgeon. The forceful lift can contribute to tissue injury and consequent complications.

This study represents an opportunity to compare tissue perfusion during breast mastectomy when using metal retractors versus fingers to lift the tissue.

Who can participate?

The study population are women 18 years of age and over, undergoing bilateral mastectomy with immediate reconstruction.

What does the study involve?

Once eligibility is confirmed the research team at the routine outpatient visit, will give a pre-operative questionnaire to be complete before surgery. On the surgery day, the surgeon will undertake the double mastectomy with breast reconstruction procedure using the retractor method in one breast and the non-retractor method (fingers) in the other breast. During the surgery, the anaesthetist will inject small amounts of the fluorescent tracer agent called Indocyanine (ICG) dye into a vein at three different time points in each breast, and at each timepoint record the tissue perfusion (%) so the difference in the blood flow between both techniques at the three different time points can be compared.

After surgery, pain scores will be collected for each breast at 18hour then again at follow up week 1, week 2 and week 4-6, during these follow up visits the research team will also collect

information regarding the secondary outcomes. At follow-up week 4-6, the participant will be also asked to complete a post-operative questionnaire.

What are the possible benefits and risks of participating?

There will be no direct benefit for the participants.

The risks associated to the study remain the same as with routine surgery, as the different surgical techniques used in this study are widely used by surgeons already, however the injection of the ICG dye is not part of the routine procedure and could be a risk of reaction to it. The information collected may benefit patients with breast cancer or at risk of breast cancer in the future.

Where is the study run from?

Cambridge University Hospitals NHS Foundation Trust (UK)

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

April 2023 to June 2025

Who is funding the study?

Addenbrookes Charitable Trust (ACT) (UK)

Innovate UK

Who is the main contact?

Alexandra Azevedo, alex.azevedo@nhs.net

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

330226

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 57311, Grant codes 10073306 / 10073066, IRAS 330226

Study information

Scientific Title

A Prospective Case-control Study to Compare Tissue Perfusion between RetrActors and Non-retractors during Immediate Breast ReConstruction

Acronym

PerfAct BreCon

Study objectives

Current Study hypothesis as of 25/03/2024:

There will be a difference in the surgery outcomes between the two tissue spread techniques used in each breast.

Previous Study hypothesis:

There will be a difference in performance between the two retractors

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 22/12/2023, East of Scotland Research Ethics Service (EoSRES) (Tayside medical Science Centre, Residency Block Level 3, George Pirie Way, Ninewells Hospital and Medical School, Dundee, DD1 9SY, United Kingdom; no telephone number provided; tay.eosres@nhs.scot), ref: 23/ES/46

Study design

Interventional case-controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast surgery

Interventions

Current interventions as of 25/03/2024:

Pre surgery:

The patient will be given the applicable modules of the BREAST-Q Reconstruction version 2.0 questionnaire to complete before their surgery takes place.

Surgery:

The mastectomy with immediate reconstruction will be undertaken as per usual local procedures. During the surgery, the anaesthetist will inject small amounts of the fluorescent tracer agent called Indocyanine (ICG) dye into a vein at three different time points in each breast. This will happen once at the beginning of surgery, once when the surgeon switches from using the non-retractor method (fingers) to metal retractors and then again at the end of the surgery. These measurements will be made in the same way in the other breast as well so the difference in the blood flow between both techniques at the three different time points can be compared.

Post surgery:

18hrs post surgery the research team will collect the pain scores from the patient for each of the breasts. Patients will be followed up during their routine clinic visits/consultation, with clinical data collection time points approximating to 1 week, 2 weeks and 4-6 weeks post surgery. At these visits the research team will collect the pain scores for each breast, information about any surgery-related adverse events the patient has experienced, information regarding re-admissions and/or re-operation. At the last post-operative time point of 4-6 weeks the patient will be given the post-operative modules of the BREAST-Q Reconstruction questionnaire to complete.

Previous interventions:

Pre surgery:

The patient will be given the applicable modules of the BREAST-Q Reconstruction version 2.0 questionnaire to complete before their surgery takes place.

Surgery:

During the mastectomy, the surgeon will request to the anaesthetist to inject dye into the patient and then the surgeon will measure the tissue perfusion using a Stryker's SPY-PHI handheld imager device at three time-points for each breast. Two different techniques will be used during surgery - non-retractors (finger dissection) in the right breast and retractors in the left breast- in order to have vision and access to the tissue to be removed. After the surgery, patients will be asked to score their pain level in each breast at four different time points; this will be either in person prior to discharge or over the telephone post-discharge.

Post surgery:

Patients will be followed up during their routine clinic visits/consultation, with clinical data collection time points approximating to 1 week, 2 weeks and 4-6 weeks post surgery. At these visits the research team will collect the pain scores for each breast, information about any surgery-related adverse events the patient has experienced, information regarding re-admissions and/or re-operation. At the last post-operative time point of 4-6 weeks the patient will be given the post-operative modules of the BREAST-Q Reconstruction questionnaire to complete.

End of trial:

End of the study will be when the last patient recruited has completed the last follow-up.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Current primary outcome measure as of 25/03/2024:

The relative difference (%) in blood perfusion between each breast in the same patient. Blood perfusion will be measured at 3 time-points (T1: baseline, T2: mid-point, T3: end) during the mastectomy procedure. The relative difference is defined as the difference, D, of Blood perfusion at T2-T1. The t-test will be applied on the between-breast difference on D.

Previous primary outcome measure:

Blood perfusion will be measured using the SPY-PHI device (%) at 3 time-points (T1: baseline, T2: mid-point, T3: end).

Key secondary outcome(s)

1. Patient hospital re-admission, where applicable; assessed through a questionnaire to the patient at following time points: Follow up week 1, week 2 and week 4-6
2. Patient hospital stay duration, where applicable; assessed through a questionnaire to the patient at following time points: Follow up week 1, week 2 and week 4-6
3. Patient re-operation required, where applicable; assessed through a questionnaire to the patient at time points: Follow up week 1, week 2 and week 4-6
4. Patient-reported post-surgery pain scores assessed on a numerical pain score at the following time points: 18hrs, follow-up week 1, week 2 and week 4-6
5. Incidence, type and severity of surgery related adverse events, where applicable; assessed through a questionnaire to the patient at following time points: Follow up week 1, week 2 and week 4-6
6. Comparison of patients' pre- and post-surgery outcomes measured in a numerical scale of the BREAST-Q Recon version 2.0 questionnaire (Modules 7, 8, 9 and 14), at follow up week 4-6

Completion date

31/01/2026

Eligibility

Key inclusion criteria

Current inclusion criteria as of 25/03/2024:

1. Signed informed consent form
2. Female aged 18 years old or above
3. Needing bilateral mastectomy for either:
 - 3.1. Bilateral breast cancer, or
 - 3.2. Risk reduction (due to pathological gene mutation or high-risk family history or previous mantle radiotherapy for lymphoma).
4. Undergoing bilateral mastectomy concurrently with immediate breast reconstruction on both sides
5. Undergoing the same type of breast reconstruction on both sides

6. Adequate liver function where bilirubin is $\leq 1.5 \times \text{ULN}$
7. Adequate renal function with a serum creatinine $\leq 1.5 \times \text{ULN}$
8. Willing and able to comply with scheduled visits and study procedures for the duration of the study.

Previous inclusion criteria:

1. Signed informed consent form
2. Female aged 18 years old or above
3. Bilateral breast cancer
4. Needing bilateral mastectomy for breast cancer or for risk reduction (due to pathological gene mutation or high-risk family history or previous mantle radiotherapy for lymphoma)
5. Undergoing bilateral mastectomy concurrently with immediate breast reconstruction
6. Undergoing the same type of breast reconstruction on both sides
7. Adequate liver function where bilirubin is $\leq 1.5 \times \text{ULN}$
8. Adequate renal function with a serum creatinine $\leq 1.5 \times \text{ULN}$
9. Willing and able to comply with scheduled visits and study procedures for the duration of the study.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

Female

Total final enrolment

32

Key exclusion criteria

Current exclusion criteria as of 25/03/2024:

1. Locally advanced breast cancer with skin involvement
2. Previous unilateral breast radiotherapy (if mastectomy is for local recurrence)
3. Previous significant unilateral breast surgery (such as reduction) judged by the recruiting /operating surgeon to have adversely affected breast supply on that side
4. Known allergies or hypersensitivity to indocyanine green (ICG) dye, sodium iodide or iodine or having experienced previous side-effects of ICG dye or its components

5. Patients with an overactive thyroid or benign tumours of the thyroid gland
6. Patients with severe renal insufficiency
7. Women who are pregnant, plan to become pregnant, or are lactating during the study period.

Previous exclusion criteria:

1. Unilateral breast cancer
2. Undergoing unilateral mastectomy
3. Not undergoing immediate breast reconstruction
4. Locally advanced breast cancer with skin involvement
5. Previous unilateral breast radiotherapy (if mastectomy is for local recurrence)
6. Previous significant unilateral breast surgery (such as reduction) judged by the recruiting /operating surgeon to have adversely affected breast blood supply on that side
7. Known allergies or hypersensitivity to indocyanine green (ICG) dye, sodium iodide or iodine or having experienced previous side-effects of ICG dye or its components
8. Patients with an overactive thyroid or benign tumours of the thyroid gland
9. Patients with severe renal insufficiency
10. Women who are pregnant, plan to become pregnant, or are lactating during the study period

Date of first enrolment

06/03/2024

Date of final enrolment

31/12/2025

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Addenbrookes Hospital

Cambridge University Hospitals NHS Foundation Trust

Hills Road

Cambridge

England

CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust

ROR

<https://ror.org/04v54gj93>

Funder(s)

Funder type

Government

Funder Name

Innovate UK

Alternative Name(s)

Technology Strategy Board

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

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1	18/12/2023	07/03/2024	No	No
Protocol file	version 2.0	22/02/2024	25/03/2024	No	No
Protocol file	version 2.1	13/06/2024	25/07/2024	No	No