ISRCTN14838482 https://doi.org/10.1186/ISRCTN14838482

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

Submission date 28/02/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 07/03/2024	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/01/2026	**Condition category** Surgery	[_] Individual participant data [X] 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
Dr Alexandra Azevedo

Contact details
Cambridge Clinical Trial Centre, S4 block, Addenbrookes Hospital, Hills Road
Cambridge
United Kingdom
CB1 0QQ
+44 1223 348 454
alex.azevedo@nhs.net

Additional identifiers

Integrated Research Application System (IRAS)
330226

Central Portfolio Management System (CPMS)
57311

Protocol serial number
Grant codes 10073306 / 10073066

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 anesthetist 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 trough 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 trough 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 trough 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 trough 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 ≤1.5 x ULN
7. Adequate renal function with a serum creatinine ≤ 1.5 x 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 < = 1.5 x ULN
8. Adequate renal function with a serum creatinine < = 1.5 x 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