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The DISC Pilot study: testing if taking extra tissue during breast surgery helps make treatment more successful

Submission date
14/01/2026

Recruitment status
Recruiting

Registration date
28/01/2026

Overall study status
Ongoing

Last Edited
28/01/2026

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Breast conservation surgery (BCS) contributes to 55% of breast cancer operations. In BCS, the cancer is removed in a lump of breast tissue (lumpectomy), and the rest of the breast is treated by radiotherapy. BCS has equal survival outcomes to mastectomy. When compared with mastectomy, BCS reduces post-operative risks, speeds up recovery and improves the psychological, physical and sexual well-being of patients. However, if the cancer reaches the lumpectomy margin/edge, patients need a second operation to remove more breast tissue. Needing a second operation causes anxiety, delays radiotherapy and worsens cosmetic outcome. The second operation is also less precise, and there is a higher risk of cancer recurrence if the margins are not clear the first time.

Previous studies for invasive breast cancer have shown that routinely taking 4 additional shavings of breast tissue around the cancer (4-quadrant cavity shaving) during the first surgery can reduce cancerous cells being left behind and reduce the need for repeat surgery to get clear margins. However, these studies have not focused on a specific type of preinvasive breast cancer called ductal carcinoma in situ (DCIS), which has a much higher risk of needing a second operation (29%) compared to invasive cancer (14%). Previous studies have also not looked at patient experience, cosmetic outcome and cancer recurrence.

Our study will therefore look specifically at DCIS. We will compare standard surgery (no routine extra shaves) to surgery that includes routine 4-quadrant cavity shaving in patients having DCIS removed in a lumpectomy. We will look for differences in the number of second operations required, post-surgery cosmetic appearance, patient experience and future breast cancer recurrence.

The study aims to see whether we can successfully run a trial looking at routinely removing a small amount of additional breast tissue known as a shave. This will be up to 1 cm wide (no thicker than a biro pen) from all edges of the lumpectomy. This may reduce the chance of cancer cells being left behind (positive margins) and the need for further surgery. We want to know what our patients think of the cosmetic outcome of their operation and what their experiences

of surgery are. This will help us to prepare for the smooth running of a larger national study with more hospitals and breast surgeons participating.

Who can participate?
Female patients who were assigned female gender at birth and are between the ages of 18 and 90 years with a new diagnosis of pre-invasive breast cancer (DCIS) only. This must be the first diagnosis of breast cancer in that breast with no previous radiotherapy.

What does the study involve?
Eligible participants will be identified in the weekly cancer multi-disciplinary team (MDT) meeting, and will be seen by a breast surgeon in clinic afterwards to discuss their diagnosis and treatment. A member of the research team will approach the patient, introduce the study and provide a participant information sheet. After some thinking time, if the patient wishes to participate in the study, they will sign a consent form. Prior to surgery, all patients will be asked complete the pre-operative questionnaire and have medical photographs of their chest taken.

On the day of surgery, patients will go through the usual pre-operative checks and start by undergoing a standard lumpectomy operation for their breast cancer. Once this is complete, the patient will be randomly allocated via a computer program to either Group A (no further breast tissue removed) or Group B (additional breast tissue removed, 4-quadrant cavity shaves). Half the patients will be assigned to group A and the other half to group B. The patients will not know which group they have been allocated to. Once the operation is completed. Recovery is the same for both groups, with patients going home on the day of the surgery if suitable.

Two weeks after surgery, the results will be discussed in the weekly MDT meeting, where it will be revealed if all the cancer has been cleared; if not, a second operation may be required. All patients will be seen in a post op results clinic to discuss the results. Post operatively, we will ask the patients to fill in the questionnaire and have medical photography of their chest at 2 further time points (4 weeks and at 1 year post op).

What are the possible benefits and risks of participating?
Benefits
Patients who are assigned to Group B and have further breast tissue removed, it may reduce the chance of leaving cancer cells behind and therefore avoid the need for a second operation. This reduces pain, shortens recovery and allows them to progress directly to radiotherapy without additional delay. The psychological stress and additional complications associated with needing further surgery are eliminated. Importantly, studies have shown that not getting clear margins at the time of the first operation is associated with worse cancer outcomes, and these patients are at increased risk of local recurrence.

Risks
Half of the patients who are assigned to Group B (additional breast tissue removed) may have additional healthy and cancer-free tissue removed unnecessarily. This may reduce the breast volume and could affect the aesthetic outcome.

Where is the study run from?
St George’s Hospital, London Rose Centre (The Breast Unit).

When is the study starting and how long is it expected to run for?
The study started recruiting in January 2026 and is expected to run a year after the last patient has been recruited.

Who is funding the study?
1. The Breast and Endocrine Fund
2. St George's Hospital Charity
3. City and St George's University of London.

Who is the main contact?
Miss Sarah Tang, Consultant Oncoplastic Breast Surgeon and Principal Investigator at St George's Hospital, London,

Contact information

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Public, Scientific, Principal investigator

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Integrated Research Application System (IRAS)

345482

Protocol serial number
19.03

Study information

Scientific Title
Ductal carcinoma in situ cavity shave (DISC) pilot randomised control trial (RCT): a feasibility study

Acronym
DISC

Study objectives
1. To perform a trial run of the study on a small scale
2. To gauge the acceptability of the trial to patients
3. To assess whether recruitment and screening processes work well
4. To establish the recruitment rates per week/month
5. To identify additional resources required to conduct the study (financial, human and time) in order to support an accurate breakdown of costs for the main trial funding application
6. To perform quality control of the data collection tools (consent forms, patient information sheets, Research Electronic Data Capture (REDCap) database, intraoperative data capture paperwork, BREAST-Q©)
7. To examine the robustness of the research methodology (randomisation process, surgical factors, histology factors)
8. To test the data analysis techniques (statistics, photographic assessment, BREAST-Q© outcomes)
9. To determine whether treatment effects/outcomes are consistent with expectation
10. To establish any challenges experienced by patient participants, the research team, clinical staff and the site
11. To provide sufficient evidence to support the running of a large scale multicentred national study

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/06/2025, Cornwall and Plymouth (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 02071048138; cornwallandplymouth.rec@hra.nhs.uk), ref: 25/SW/0044

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Single-centre interventional single-blinded randomised controlled trial.

Random allocation using a computer-generated random allocation program. All staff and patients will be masked to the group allocation until the day of surgery. The surgeon will remain masked until they have conducted their standard of care operation. After this, the group allocation will be revealed. The patient will remain blinded to the allocation. The control group will be Group A, which is the standard of care group.

Intervention will be surgical. In one arm of the study, the patient will undergo standard-of-care breast-conserving surgery (wide local excision) as per the usual protocol (Group A). The intervention arm of the study (group B) patients will undergo standard of care, standard breast conserving surgery (wide local excision) PLUS additional four-quadrant cavity shaves.

Comparative Arms of Study

The two arms are as follows:

1. Control group- Group A - standard WLE (no four-quadrant cavity shaves)
2. Intervention group- Group B -standard WLE plus four-quadrant cavity shaving (further shaves)

Patients will be randomised using the REDCAP independent randomisation program to allocate to group A or B on a 1:1 basis. The additional surgical time for the cavity shaves in patients assigned to Group B is anticipated to be up to 10 minutes. Measurements of all the shaves, including weight, length, width and depth, will be taken and documented prior to fixation with formaldehyde. The samples will all be assessed in accordance with the Human Tissue Act within the pathology department. The patient will remain blinded throughout the trial process, including up to 1 year after surgery, this is to prevent bias when they provide feedback on the aesthetic outcome. The surgeon will remain blinded until the point they complete their standard of care wide local excision. After this point, the allocation group the patient has been assigned to will be revealed. This is to reduce surgical bias when conducting the operation.

Intervention Type
Procedure/Surgery

Primary outcome(s)

1. The number of patients eligible for the study measured using data provided by the coordinator at the MDT at a weekly meeting over 9 months

2. The percentage of patients with breast cancer diagnoses who meet the inclusion criteria measured using data provided by the coordinator and cross-referenced at a weekly MDT meeting over 9 months

3. The percentage of patients who meet eligibility criteria and agree to be included in the study measured using data collected from medical records from pathology in the clinic setting at a monthly time point over 9 months

4. Percentage of patients who complete the Breast-Q questionnaire measured using study data at pre-op, 4 weeks and 1 year post op

5. Percentage of patients who undergo chest wall photography measured using study data at pre-op, 4 weeks and 1 year post op

Key secondary outcome(s))
1. Patient feedback on participation and patient information sheet measured using a questionnaire at 1 year post op

2. Additional theatre time (in minutes) required to perform additional surgery (Group B) measured using study data at 4 weeks post op

3. Additional cost associated with histology processing of tissue in Group B patients measured using study data at 4 weeks post op

4. Surgeon feedback on study experience (randomisation process, challenges identified) measured using a questionnaire at 1 year post study opening

5. Simple comparative analysis of specimen weights, margin measurements, re-excision rates and cosmetic outcomes to determine whether treatment outcomes are consistent measured using study data at 1 year after last patient is recruited

Completion date
24/10/2026

Eligibility

Key inclusion criteria
1. Female gender as determined at birth
2. Age 18 years and above
3. Primary breast cancer
4. Unilateral disease
5. Bilateral disease (DCIS in each breast)
6. Unifocal disease in each breast
7. Breast cancer which is DCIS on pre-operative histology, no invasive component
8. First diagnosis of primary breast cancer in that breast
9. Eligible for breast conserving therapy
10. Standard wide local excision technique
11. No previous radiotherapy to the breast

12. Demonstrates capacity to consent as assessed by their primary clinician
13. The perioperative use of any lesion localisation method including but not restricted to metal wires, localisation seeds (Magseed® Endomag), intraoperative use of the Faxitron (free standing x-ray machine) or other specimen x-ray machines

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
90 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Male gender
2. Patients with multifocal disease that requires mastectomy
3. Communication issues or limited English.
4. Previous breast cancer in the ipsilateral breast that has undergone the following treatments: endocrine therapy, WLE/radiotherapy
5. WLE that would include therapeutic mammoplasty and chest wall perforator flaps
6. Patients undergoing WLE under local anaesthetic
7. Patients that have had previous cosmetic augmentation/corrective surgery or reduction mammoplasty

Date of first enrolment
09/01/2026

Date of final enrolment
26/09/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St George's University Hospital, NHS Foundation Trust
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Sponsor information

Organisation
City St George's, University of London

ROR
https://ror.org/047ybhc09

Funder(s)

Funder type
Not defined

Funder Name
Breast and Endocrine Research Fund, St George's Hospital Charity

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. This will be in the REDCAP database then transferred and stored securely on a password encrypted NHS computer.

The datasets generated and /or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication, Stored in non-publicly available repository