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A feasibility study comparing vacuum drainage with a surgical cut to treat breast abscesses

Submission date
23/09/2026

Recruitment status
Recruiting

Registration date
02/11/2026

Overall study status
Ongoing

Last Edited
02/11/2026

Condition category
Skin and Connective Tissue Diseases

[_] 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

A breast abscess is a painful collection of infected fluid or pus in the breast. It can occur during breastfeeding and may need to be drained to help the infection settle. One way to do this is through surgery, where a cut is made in the breast to drain the pus. However, surgery can leave a visible scar and may affect the shape of the breast.

This study is looking at another treatment called vacuum-assisted drainage. This uses a small tube and gentle suction to remove the infected fluid. The researchers want to find out whether it is practical and acceptable to compare vacuum-assisted drainage with surgery in a randomised study. They will also look at quality of life, pain, how quickly symptoms improve, whether further treatment is needed, and women's experiences of treatment. The findings will help the researchers plan a larger study in the future.

Who can participate?

Women aged 18 years or older with a breast abscess confirmed by an ultrasound scan may be able to take part. The abscess must be larger than 5 cm, have more than one pocket of infected fluid, or have already been unsuccessfully treated with needle drainage.

Women cannot take part if, for example, they have breast cancer, certain other types of breast inflammation or abscess, skin damage that requires surgery, or a condition or treatment that increases their risk of bleeding.

What does the study involve? (for participants)

The study aims to recruit 70 women from 26 hospitals. Participants are randomly allocated to receive either vacuum-assisted drainage or surgical drainage.

Vacuum-assisted drainage is usually carried out under local anaesthetic in an outpatient setting. A small cut of about 5 to 6 mm is made in the skin. A vacuum drainage device is then guided into the abscess using an ultrasound scan, and gentle suction is used to remove the infected fluid. Participants can usually return home soon afterwards if there are no immediate problems.

Surgical drainage usually requires admission to hospital and is normally carried out under general anaesthetic. A cut is made in the breast to drain the abscess. The area is cleaned and a drain is usually left in place for several days. Participants return home when they are well enough.

Participants in both groups are followed up to check their recovery and wound healing and to

make sure that the abscess has not returned. Quality of life is assessed before treatment and 3 months afterwards. Pain during the procedure, how long symptoms take to improve, further treatment, breastfeeding and healthcare costs are also assessed. Some patients and clinicians will be invited to take part in interviews about their experiences of the treatment and study.

What are the possible benefits and risks of participating?
Both treatments are designed to drain the breast abscess and help the infection settle. Vacuum-assisted drainage may avoid a larger surgical cut and a general anaesthetic. However, it is not yet known whether vacuum-assisted drainage is better than surgery, which is why this study is being carried out.
Possible problems include pain, bleeding, problems with wound healing, the abscess returning, or the treatment not fully draining the abscess. Some participants may need further treatment. Surgery may also result in scarring or changes to the shape of the breast.

Where is the study run from?
The study is being carried out in England. Participating centres listed in the study record include Imperial College Healthcare NHS Trust at St Mary's Hospital in London and Gateshead Health NHS Foundation Trust at Queen Elizabeth Hospital in Gateshead (UK).

When is the study starting and how long is it expected to run for?
September 2026 to June 2028.

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

Who is the main contact?
Professor Daniel Leff, d.leff@imperial.ac.uk

Contact information

Type(s)
Principal investigator, Scientific, Public

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Integrated Research Application System (IRAS)
341029

Study information

Scientific Title
A randomised controlled trial of radiological vacuum drainage compared with surgical incision drainage for large, multiloculated or needle aspiration-resistant breast abscesses, assessing patient satisfaction at 3 months following intervention

Acronym
MAMMA-VAD

Study objectives
Our main aim is to establish the feasibility of a RCT and to investigate UK wide variation in outcomes following VAD that are vital to informing the design of a future trial. We aim to determine the number of eligible patients, confirm acceptability of randomisation and assess retention and attrition. We also aim to capture differences in quality of life outcomes and time to symptom resolution between VAD and surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/06/2026, Health Research Authority, London - Bromley Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8118; bromley.rec@hra.nhs.uk), ref: 26/LO/0386

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Basic science, Health services research

Study type(s)

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

Interventions

Vacuum-Assisted Drainage (Intervention arm):
Vacuum drainage of the breast abscess. Vacuum drainage is performed under local anaesthetic in an outpatient setting, typically in a dedicated suite within the radiology department or the breast unit. 10-20 ml of 1% lidocaine with 1:200,000 adrenaline is infiltrated into the skin and deeper tissues surrounding the breast abscess under ultrasound guidance.
A small skin incision (5-6mm) is made to facilitate entry of the vacuum device. Next, the needle of the vacuum device is inserted through the skin incision into the breast abscess under ultrasound guidance. Then, using either continuous or intermittent “suction/VAC” mode the abscess is evacuated through the device until all pus has disappeared on the ultrasound image. It is not essential to leave a drain as it does not impact on time to resolution of symptoms . The patient is discharged home soon after the procedure provided there are no immediate complications (e.g. bleeding).
Follow-up continues on an outpatient basis to ensure there is no recurrence and to check on wound healing.

Control (standard care) arm:
Standard care is surgical incision drainage. This typically involves hospital admission. Patients requiring surgical incision drainage are commonly converted from oral to intravenous antibiotics. The patient is kept nil by mouth and placed on an emergency operating list.
The surgical procedure is typically performed under general anaesthesia, and involves placing a surgical incision in the skin, followed by entry into the abscess cavity and physical release of the pus. The incision is typically placed in a radial skin crease at the most dependent part of the abscess. The abscess cavity is then irrigated with saline and/or aqueous antiseptic solution.
A corrugated drain is inserted into the abscess cavity and the wound is then closed around the drain. The drain is slowly released over a number of days to encourage the cavity to heal upwards from the inside out.
Following the procedure, the patient is discharged home when pain allows. Oral antibiotics are prescribed on discharge from hospital to ensure a full treatment course.
Follow-up continues on an outpatient basis to monitor drainage, check wound healing and exclude recurrent abscess formation.

Follow-up for both arms: 3 months after the intervention. Assessments are done at baseline and at 3 months. The vacuum-assisted drainage arm also has an ultrasound at 1 week after intervention.

Randomisation: 1:1, computer-generated, using a validated web-based system (REDCap). Site staff randomise participants online once eligibility and consent have been confirmed.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Breast-related quality of life measured using the Modified BREAST-Q at baseline and 3 months following intervention

2. General quality of life measured using the EQ-5D-5L at baseline and 3 months following intervention

3. Periprocedural pain measured using a visual analogue scale at during the procedure

Key secondary outcome(s)
1. Time to resolution of symptoms measured using data entered into the REDCap eCRF by the local research team, cross-checked against medical records, at 3 months post-intervention
2. Treatment failure measured using review of medical records at 3 months post-intervention. Resolution in the vacuum-assisted drainage arm is also assessed by ultrasound at 1 week
3. Need for repeated interventions measured using review of medical records at 3 months post-intervention
4. Cessation of lactation measured using a study-specific lactation survey at 3 months post-intervention
5. Deviations from exclusively feeding with the breast measured using a study-specific lactation survey at 3 months post-intervention
6. NHS costs, including the cost of the intervention, antibiotics, dressings, hospital care and treatment of complications, measured using the ModRUM health resource use questionnaire and review of medical records at 3 months post-intervention
7. Acceptability of the intervention and its implementation measured using qualitative interviews with up to 30 patients and up to 30 clinicians at baseline and 3 months following intervention
8. Barriers to implementation measured using qualitative interviews with up to 30 patients and up to 30 clinicians at baseline and 3 months following intervention
9. Facilitators to implementation measured using qualitative interviews with up to 30 patients and up to 30 clinicians at baseline and 3 months following intervention

Completion date
07/06/2028

Eligibility

Key inclusion criteria
1. Female
2. 18 years or older
3. Confirmed breast abscess on ultrasound scan imaging
4. Breast abscess size >5cm, and/or multiloculated, and/or that has one failed attempt at 19G needle aspiration

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Female

Total final enrolment

0

Key exclusion criteria
1. Concurrent breast cancer diagnosis
2. Cancerous mastitis
3. Biopsy confirmed granulomatous infection
4. Periductal non-lactational abscess
5. Skin necrosis requiring surgical debridement
6. Anticoagulation or bleeding dyscrasias

Date of first enrolment
07/09/2026

Date of final enrolment
07/03/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
South Wharf Road
London
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Study participating centre
Gateshead Health NHS Foundation Trust
Queen Elizabeth Hospital
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Sponsor information

Organisation

Imperial College Healthcare NHS Trust

ROR
https://ror.org/056ffv270

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