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Is it possible to run a clinical research study to investigate the role of mesh in implant-based breast reconstruction surgery?

Submission date
19/06/2023

Recruitment status
No longer recruiting

Registration date
20/10/2023

Overall study status
Completed

Last Edited
21/10/2025

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Breast cancer affects one in eight women. 55,000 women are diagnosed in the UK per year. Over 40% of women needing surgery require mastectomy and may be offered breast reconstruction with an implant if suitable. Since 2015, surgeons have been using a mesh to provide additional cover and support to the implant placed on the chest wall muscles for cosmesis. Mesh costs up to £2500 per breast and uncertainty exists about its benefits and risks to patients. Meshes have been reported in academic literature to potentially increase certain post-operative problems (complications) whereas the mesh industry reports benefits.
We do not have good-quality evidence to guide patients on the risks and benefits of using mesh in breast reconstruction. Therefore, we cannot determine whether using mesh or not is better. Surgeons do have alternative techniques to using mesh which have been shown to be safe. If breast reconstruction is acceptable without mesh, patients may avoid complications associated with mesh use. The NHS could divert resources from mesh towards other patient needs.
The best way to evaluate mesh is a randomised controlled trial (RCT) where we compare the health of the women who receive different treatments to decide which is cost-effective. This type of study can be challenging and costly; currently we do not know if women and surgeons are willing to take part.
The aim of this study is to carry out a feasibility trial to evaluate breast reconstruction surgery without and with mesh in patients requiring mastectomy to proceed to a definitive RCT.

Who can participate?
Women aged 19 years and over who have decided with their surgeon to proceed to an immediate prepectoral (above the muscle) implant-based breast reconstruction after mastectomy (for cancer treatment or risk reduction).

What does the study involve?
Participants will be asked to fill in a questionnaire before their surgery and on the day of surgery will be randomly allocated to either receive an implant-based breast reconstruction with mesh or without mesh in the above muscle position (prepectoral). After surgery participants will be told which operation they had on day 90 of their recovery, after completing a post-operative

questionnaire. There are two sub-studies which participants will also be offered to participate in: having an interview with a researcher about their views on mesh and the study design, and having breast movement before and after surgery (biomechanics) measured at the University of Portsmouth.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
March 2021 to August 2025

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

Who is the main contact?
Ms Rachel Rolph, rachel.rolph@nds.ox.ac.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-mesh-assisted-breast-implant-reconstruction-surgery-restore-b

Contact information

Type(s)
Principal investigator

Contact name
Ms Rachel Rolph

ORCID ID
https://orcid.org/0000-0002-1425-4322

Contact details
St Johns' College,
University of Oxford
Oxford
United Kingdom
OX1 3JP
+44 (0)1865 227374
rachel.rolph@sjc.ox.ac.uk

Type(s)
Scientific

Contact name
Mr Charles Maylon

Contact details
Surgical Trials Intervention Unit (SITU)
Nuffield Department of Surgical Sciences
John Radcliffe Hospital
Headington

Oxford
United Kingdom
OX3 9DU
+44 (0)1865 612268
restoreb@nds.ox.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT06112977

Integrated Research Application System (IRAS)
301423

Central Portfolio Management System (CPMS)
58112

Study information

Scientific Title
A mixed-methods multi-centre randomised controlled trial comparing no-mesh to mesh-assisted breast reconstruction surgery: the Restore-B (NoMesh) Study

Acronym
Restore-B

Study objectives
Is it feasible to run a large multi-centre randomised single blinded controlled trial comparing immediate prepectoral breast reconstruction (expander or implant based) with and without the use of mesh (synthetic or biological).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/10/2023, South Central – Hampshire B Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)207 104 8088, +44 (0)207 104 8289, +44 (0)207 104 8189; hampshireb.rec@hra.nhs.uk), ref: 23/SC/0302

Primary study design
Interventional

Study design
Multicentre prospective single-blinded randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mastectomy for treatment or prevention of breast cancer

Interventions
Randomisation will be a 1:1 allocation between the two intervention arms via the online database REDcap. Participants are randomised to immediate breast reconstruction using an implant or expander in the prepectoral plane with or without the use of surgical mesh (synthetic mesh or biological acellular dermal matrix). Patients will be blinded to their allocation. Feasibility outcome data alongside patient-reported quality of life and clinical complication data will be collected. A provisional economic analysis of the two arms alongside a blinded cosmetic assessment will be performed.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Feasibility outcomes measured using quantitative trial database:
1. Number of women eligible for the study in 12 months
2. Number of women recruited in 12 months
3. Number of women randomized in 12 months
4. Number of women blinded to 90 days in 12 months

Key secondary outcome(s)
1. Clinical outcome measures, measured using patient medical records at 90 days: number of women with the following: infection (requiring treatment), seroma (requiring drainage), reoperation, haematoma, mesh removal, implant removal
2. Patient-reported quality of life measured by EQ5D and Breast Q questionnaires pre- and post-operatively at 90 days
3. Aesthetic scoring: blinded independent assessment of interventions by a panel of health professionals at 90 days postoperatively
4. Exploratory economic analysis of two arms using weekly patient reported diaries from day 7-90 postoperatively

Completion date
31/08/2025

Eligibility

Key inclusion criteria
1. Women aged >18 years
2. Participant is willing and able to give informed consent for participation in the trial
3. Eligible for prepectoral implant-based breast reconstruction with implant or expander with mesh (synthetic or biologic) for cancer treatment or risk reduction surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
19 Years

Sex
Female

Key exclusion criteria
1. Participant is pregnant, lactating or planning pregnancy during the trial
2. Patient refusal
3. Delayed breast reconstruction following simple mastectomy

Date of first enrolment
01/11/2023

Date of final enrolment
31/08/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford University Hospitals
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
The Royal Marsden Hospital
Fulham Road
London
United Kingdom
SW3 6JJ

Study participating centre
Royal Marsden Hospital
Royal Marsden Hospital
Downs Road
Sutton

United Kingdom
SM2 5PT

Study participating centre
University Hospital Southampton
Southampton University Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Portsmouth Hospitals University National Health Service Trust
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Uclh
250 Euston Road
London
United Kingdom
NW1 2PQ

Study participating centre
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

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

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		17/10/2025	21/10/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes