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Is implant placement under or above the chest muscle best in immediate breast reconstruction?

Submission date 25/08/2020	**Recruitment status** Stopped	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/01/2021	**Overall study status** Stopped	
Last Edited 05/08/2025	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
A mastectomy is an operation to remove a breast. A mastectomy may be recommended if cancer is in a large area of the breast; cancer has spread throughout the breast, or the breast is full of pre-cancerous cells. Breast reconstruction is an operation to make a replacement for the tissue removed during a mastectomy. It's often done at the same time as a mastectomy, but it can be done at a later date.
There are two ways in which implants can be placed during implant-based breast reconstruction; the implants can be placed under the chest muscle (a subpectoral implant) or placed on top of the chest muscle (pre-pectoral implant). Both are standard procedures commonly performed across the UK but currently here is currently no good evidence which implant procedure is best for patients
This study will test whether subpectoral or pre-pectoral implant placement improves women's satisfaction with the outcome of their reconstruction in a small trial, to test if it is feasible to carry out a larger trial later.

Who can participate?
Women aged 18 years or older, who require a mastectomy for breast cancer or risk-reduction.

What does the study involve?
Participants will be randomly allocated into two equal groups. One group will have a subpectoral implant-based breast reconstruction and the other will have a pre-pectoral implant-based breast reconstruction. We also want to capture how information about the study is given to patients. This will help us understand how research studies are explained to people and if there are any improvements we can make.

What are the possible benefits and risks of participating?
This study will not benefit patients directly but the information provided will help to improve the future management of patients who undergo implant breast reconstructive surgery. Also, some people enjoy being part of a research study because of the close contact with research staff and their opportunity to share their opinions and experiences of their condition and treatments.
Risks- There should be no additional risks to routine NHS practice of either implant-based

reconstruction procedure, and neither are new or experimental. The participant will have the same risks as anyone having immediate implant-based reconstruction

Where is the study run from?
Southmead Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2020 to August 2023

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

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
279460

Protocol serial number
IRAS 279460, CPMS 46954

Study information

Scientific Title
Is subpectoral or pre-pectoral implant placement Best in immediate BReAst reconstruction? The Best-BRA Pilot Trial

Acronym
Best-BRA pilot

Study objectives
Pre-pectoral implant based breast reconstruction (IBBR), a ‘muscle sparing’ technique which involves the wrapping of the implant in mesh and placing it on top rather than underneath the pectoralis muscle may improve patient outcome compared to subpectoral (under the muscle) IBBR and it is becoming increasingly popular. There is however, a lack of high-quality evidence to support the effectiveness of either of these techniques. Before a large-scale trial is conducted, we first need to address whether surgeons will recruit patients to a randomised study comparing two approaches to IBBR and whether patients will consent to be randomised and agree to receive their allocated treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/01/2021, Wales REC 6 (Floor 4, Institute of Life Science 2, Swansea University, Swansea, SA2 8PP; +44 (0)7920 565 664; Wales.REC6@wales.nhs.uk), ref: 20/WA/0338

Study design
Pragmatic two-arm external pilot randomised controlled trial with QuinteT Recruitment Intervention (QRI) and economic scoping

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Implant-based breast reconstruction following mastectomy for breast cancer or risk reduction

Interventions
Women who require a mastectomy for either breast cancer or risk reduction and elect to have an IBRR will be recruited and randomised 1:1 for either a subpectoral or pre-pectoral implant reconstruction with mesh. Patients will then receive standard care as per clinical guidelines and be followed-up for 12 months.

A QRI will be used to identify recruitment challenges and optimise recruitment to the trial. Best-BRA will assess the feasibility of a future, multi-centre randomised controlled trial to determine the most clinically effective and most cost-effective IBBR technique.

Randomisation- The randomisation sequence will be generated by the Bristol Medical School's REDCap database randomisation system. Participants will only be randomised after eligibility and consent have been confirmed. Patients will be randomly allocated to the techniques in a 1:1 ratio stratified by hospital. Randomisation within blocks of varying size will prevent large imbalances in the number of patients in each treatment arm. Randomisation will occur at the final clinic visit prior to admission for surgery. Access to the allocation will be by a web-based system and the allocation will be concealed until the patient has been logged into the system and a study ID number generated so ensuring that judgements about eligibility are made without knowledge of the next allocation (allocation concealment). The unit of randomisation will be the patient. Those women having bilateral mastectomy and IBBR will have the same procedure on each side (i.e. either pre-pectoral or subpectoral) within the study. The surgeon will be informed of the patient's treatment allocation following randomisation to allow them to plan theatre lists and ensure sufficient operating time is available.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Assessed throughout the duration of the trial using screening logs:
1. Recruitment into trial (number of sites recruiting; proportion of eligible women approached that are randomised, women recruited per site per month)
2. Adherence to trial allocation by comparing number of women allocated to trial intervention vs. their actual reconstruction (i.e pre-pec or subpectoral IBBR)
3. Completion rates measured by overall data completeness (% missing data)

Key secondary outcome(s))
1. Satisfaction with breasts using the validated BREAST-Q questionnaire at 12 months
2. Surgical complications, in particular implant loss, infection, re-admission and reoperation measured using patient records at 3 and 12 months
3. Need for additional surgery to the reconstruction or the contralateral breast measured using patient records at 12 months
4. Pain scores assessed using a visual analogue scale (VAS) at 24 hours and 1 week
5. Objective cosmetic outcome at 12 months assessed using routinely collected patient photographs
6. EQ-5D-5L health-related quality of life score at 12 months
7. Wellbeing (ICECAP-A) score at 12 months
8. Patient-reported outcome domains included in the breast reconstruction core outcome set

including physical well-being (chest); emotional well-being; and animation assessed using appropriate subscales of the BREAST-Q at 12 months
9. Cost-effectiveness of pre-pectoral and subpectoral IBBR assessed by micro-costing the two procedures. Data will be gathered from electronic notes/medical records as well as routine data

Completion date
31/08/2023

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Aged 18 years or above
2. Require a mastectomy for breast cancer or risk-reduction
3. Elect to undergo immediate IBBR
4. Considered eligible for either pre or subpectoral reconstruction by the surgical team

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
11

Key exclusion criteria
1. Had a delayed reconstruction
2. Has had revision breast reconstruction surgery

Date of first enrolment
26/07/2021

Date of final enrolment
31/01/2023

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Bristol
United Kingdom
BS10 5NB

Study participating centre
Hemel Hempstead Hospital
West Hertfordshire Hospitals NHS Trust
Hillfield Road
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United Kingdom
HP2 4AD

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Wayside House
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Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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

Funder Name
NIHR Academy; Grant Codes: CS-2016-16-019

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 publically available repository. Anonymous data sets will be made 'open data' following publication and stored in the University of Bristol's Research Data Storage Facility (RDSF). (http://www.bristol.ac.uk/acrc/research-data-storage-facility)

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		30/11/2021	24/01/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other unpublished results			05/08/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes