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The pre-pectoral breast reconstruction evaluation study

Submission date 01/03/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/05/2019	**Overall study status** Completed	
Last Edited 26/02/2025	**Condition category** Surgery	

Plain English Summary
Background and study aims
55,000 women are diagnosed with breast cancer each year in the UK. 40% undergo mastectomy (surgical removal of the breast) and of those who choose breast reconstruction, most will have an implant-based operation.
Traditionally, implant-based reconstructions have been performed by placing the implant under the chest wall (pectoral muscle) with or without a biological or synthetic mesh to support it. This gives a good result but lifting the muscle can be painful and some women dislike the upward movement of the implant that is seen when the chest wall muscle contracts often called implant 'animation'.
Recently new techniques have been introduced in which the implant wrapped in mesh is placed on top of, rather than under the muscle. These techniques called prepectoral implant reconstruction may be less painful and may give more natural-looking results as well as avoiding problems with implant animation.
Although these techniques are gaining in popularity, there is no good evidence to suggest that they are as safe or effective as standard submuscular reconstruction. Ideally, the two techniques should be fairly compared in a randomised trial but the prepectoral technique is still changing and only a limited number of surgeons are able to offer this to patients. Before a trial can be considered it is necessary to:
1. Determine whether prepectoral techniques are safe by measuring complications including the need to remove the implant at 3 months
2. Explore whether the technique has stopped changing and is now stable and ready for evaluation
3. Create a network of surgeons who are able to perform prepectoral reconstructions and could take part in a future trial

Who can participate?
Women aged over 16 undergoing mastectomy for breast cancer or risk reduction and electing to undergo immediate prepectoral implant-based breast reconstruction

What does the study involve?
Patients will be asked to sign a consent form and complete questionnaires before the operation. They will have an operation and see a surgeon and their team as normal following surgery.

Patients will be asked to complete postoperative pain scores at 24 hours, 48 hours, 1 week following surgery and quality of life and satisfaction questionnaires at 3 and 18 months after their operation. These can be completed online or paper according to patient preference The questionnaires should take no more than 30 minutes to complete.

What are the possible benefits and risks of participating?
There are no benefits to individual participants, but the information collected during the study might help women make choices regarding breast reconstruction in future. There are no risks involved in trial participation beyond the inherent risks of surgery, which will be explained by individual surgeons and are independent of the study.

Where is the study run from?
University of Bristol and 37 recruiting sites (UK)

When is the study starting and how long is it expected to run for?
October 2017 to September 2022

Who is funding the study?
1. The Bristol NIHR Biomedical Research Centre (UK)
2. The Royal College of Surgeons of England (UK)
3. The Association of Breast Surgeons (UK)

Who is the main contact?
Miss Shelley Potter
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Study website
https://www.bristol.ac.uk/population-health-sciences/centres/surgical-research/research/pilot/pre-bra/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2.0

Study information

Scientific Title
The Pre-pectoral Breast Reconstruction Evaluation Feasibility Study - a mixed-methods IDEAL 2a /2b prospective cohort study to determine the safety and effectiveness of pre-pectoral implant-based breast reconstruction

Acronym
Pre-Bra

Study hypothesis
Current study hypothesis as of 08/04/2020:
Pre-pectoral breast reconstruction is safe and the technique is stable and ready for evaluation in a definite randomised controlled trial.

Previous study hypothesis:
Pre-pectoral breast reconstruction is safe and results in levels of pain and implant animation following surgery which are acceptable to patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/05/2019, NHS HRA South Central - Oxford B Research Ethics Committee (Whitefriars, Level 3, Block B, Lewin's Mead, Bristol, BS1 2NT; 0207 104 8168; nrescommittee.southcentral-oxfordb@nhs.net), ref: 19/SC/0129, HRA/HCRW approval 14/05/2020

Study design
Mixed methods IDEAL 2a/2b prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request participant information sheet

Condition
Breast reconstruction

Interventions
It is anticipated that patients entering the study will be followed up for 18 months.

Screening (using SEAR method)
Screening data will not include any patient identifiable information:
1. All patients electing to undergo IBBR
2. Number technically suitable for PPBR
3. Number not considered technically suitable for PPBR and reasons for this
4. Number accepting PPBR
5. Number accepting study participation

Baseline pre-operative assessment
1. Patient demographic data captured
2. BREAST-Q completed (Reconstruction-pre-operative version)

Surgical admission
1. PPBR procedure: operative data captured
2. Length of post-operative hospital stay
3. Post-operative pain at 24 hours or point of discharge
4. Any immediate in-hospital complications

Early clinical follow-up
1. Post-operative pain score at 1 and 2 weeks electronically self-reported by the patient if no longer in hospital
2. Assessment and recording of complications at clinical review: timing as per each site's routine standard of care follow-up arrangements
3. Oncological data and planned adjuvant treatment (if appropriate)

3-month data
1. Assessment of complications including re-admission and re-operation if these events occur
2. Information taken from clinical notes and in discussion with each site's research team
3. Pain Scores electronically self-reported by the patient at 3 months
4. PROMs: Breast-Q reconstruction – satisfaction with information; patient reported complications

18-month data
1. BREAST-Q completed (Reconstruction-pre-operative version)

Added 23/04/2020:
The intervention is prepectoral implant-based breast reconstruction performed according to local surgeons' standard practice.
This is a multicentre prospective cohort study. The researchers will collect baseline demographic, operative, oncological and complication data at 3 and 18 months. Patients will complete validated patient-reported outcome questionnaires (BREAST-Q) preoperatively and at 3 and 18 months following surgery. Pain scores will be measured using a VAS at 24 hours, 1 week and 3 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measure as of 08/04/2020:
Implant loss rate at 3 months defined as: any unplanned removal of the implant without replacement of the prosthesis (implant or expander) for infection, wound problems or other indication within the first 3 months following surgery

Previous primary outcome measure:
Implant loss rate at 3 months will be determined by clinical review carried out by participating surgeons at participating clinical sites. Implant loss is defined as: "any unplanned removal of the implant without replacement of the prosthesis (implant or expander) for infection, wound problems or other indication within the first 3 months following surgery."

Secondary outcome measures
Current secondary outcome measures as of 08/04/2020:
1. Other key safety measures including infection, return to theatre and reoperation, measured by clinical review at 3 months
2. Post-operative pain scores measured by VAS at 24 hours, 48 hours, 1 week and 3 months
3. Patient satisfaction with the outcome of their reconstruction assessed using the 'satisfaction with breasts' domain of the BREAST-Q at 18 months
4. Other patient-reported outcomes included in the breast reconstruction core outcome set including physical function, emotional well being and animation assessed using the BREAST-Q at 18 months
5. The feasibility of using mixed methods to promote shared learning and determine if the procedure is sufficiently stable for evaluation in the context of an RCT
6. The proportion of surgeons reporting modifications/complications; of these
7. The proportion of CRFs including details of modifications or learning arising from complications; of these
8. The proportion of surgeons agreeing to be interviewed; and of these
9. The proportion of interviews performed

Previous secondary outcome measures:
1. Safety will be determined by comparing key safety outcomes for pre-pectoral breast reconstruction including infection; return to theatre and readmission at 3 months with published national audit data. All 3 measures will be determined by clinical teams and reported to the central study team as they occur. Definitions of all 3 measures are:
1.1. Infection- A hot, red swollen breast associated with one of the following; a temperature, pus at the wound site, a raised white cell count and/or; a positive wound swab within the first 3 months following surgery. This will be further classified as:

1.1.1. Minor – requiring oral antibiotics only;
1.1.2. Major 1 – requiring admission for IV antibiotics and/or debridement;
1.1.3. Major 2 – requiring surgical drainage/debridement
1.2. Readmission to hospital– any re-admission to hospital in the 3 months following surgery directly related to the procedure (e.g. with infection requiring antibiotics).
1.3. Return to theatre – Return to the operating theatre at any time during the first 3 months following surgery to deal with any complication of the reconstruction. This will not include any secondary oncological procedures such as axillary clearance or planned procedures including exchange of expander for a fixed volume implant or lipo-modelling.
2. The feasibility of using mixed methods to promote shared learning and identify when the technique is sufficiently stable for evaluation in the context of an RCT will be determined by:
2.1. The number of surgeons reporting modifications to their patient selection criteria or technique, or a post-operative complication via individual patient case report forms (CRFs). Each time one of these events occur, surgeons will be contacted and invited to take part in qualitative interviews to explore these events in further detail. The number of surgeons reporting events via CRFs and agreeing to qualitative interviews will determine the feasibility of these novel methods.
3. The feasibility, design and conduct of a future RCT will be determined by exploring the numbers of patients potentially eligible for pre-pectoral reconstruction; the types and frequencies of products used and approaches to concomitant interventions. This will be measured by:
3.1. Before the study - A national practice survey of both clinical sites and individual surgeons to determine how widely pre-pectoral breast reconstruction (PPBR) is practiced and how widely the technique varies from the point of view of products used and approaches to concomitant interventions (e.g. use of surgical drains and antibiotics) at the start of the study.
3.2. During the study - detailed screening logs will be kept at each clinical site of how many cases are suitable for implant-based breast reconstruction (IBBR), and within this group how many of those would be technically suitable for PPBR? And of those suitable for PPBR, how many go on to have the technique and if they don't choose to, their reasons. This will inform the feasibility of potentially randomising between IBBR and PPBR in a future study.
3.3. At the close of the study - how many surgeons have taken part, what proportion have engaged with qualitative interviews. And how many surgeons report (via individual patient CRFs) that sequential operations they have performed have not been modified i.e. the procedure is stable, and can be evaluated in a randomised controlled trial.
4. The capacity to deliver a future RCT will be determined by the success of 1, 2 and 3

Overall study start date
01/10/2017

Overall study end date
30/09/2022

Eligibility

Participant inclusion criteria
Consecutive women >16 who require a mastectomy for breast cancer or risk-reduction who:
1. Elect to undergo immediate implant-based breast reconstruction
2. Considered suitable for PPBR by their surgeon
3. Understand and accept that PBRR is innovative and that outcome data are limited

Participant type(s)

Patient

Age group
Adult

Sex
Female

Target number of participants
341

Total final enrolment
347

Participant exclusion criteria
Absolute exclusion criteria:
1. Thin/ insufficiently vascularised skin-flaps as assessed by the operating surgeon
2. Revision /delayed breast reconstruction

Additional relative exclusion criteria applied in line with the ABS/BAPRAS guidelines for mesh-assisted breast reconstruction for surgeons in the learning phase or early practice of prepectoral breast reconstruction:
1. Smokers or ex-smokers <6 weeks
2. Previous radiotherapy to the ipsilateral breast/chest wall
3. BMI >30 (except for dermal sling procedures)
4. Implant size >600cc
5. Anticipated post-mastectomy radiotherapy
6. Poorly controlled diabetes

Recruitment start date
28/05/2019

Recruitment end date
31/12/2020

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
North Bristol NHS Foundation Trust
Southmead Hospital

Bristol
United Kingdom
BS10 5NB

Study participating centre
Royal Liverpool & Broadgreen University Hospital NHS Trust
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Pennine Acute Hospitals NHS Trust (Wythenshawe)
North Manchester General Hospital
Delaunays Rd
Crumpsall
Manchester
United Kingdom
M8 5RB

Study participating centre
Poole Hospitals NHS Foundation Trust
Longfleet Rd
Poole
United Kingdom
BH15 2JB

Study participating centre
East Kent Hospitals University NHS Foundation Trust
Ethelbert Rd
Canterbury
United Kingdom
CT1 3NG

Study participating centre
Cwm Taf Morgannwg University Health Board
Albert Road
Pontypridd
United Kingdom
CF37 1LB

Study participating centre
Yeovil District Hospital NHS Foundation Trust
Higher Kingston
Yeovil
United Kingdom
BA21 4AT

Study participating centre
Hywel Dda University Health Board (Prince Phillip)
St Davids Park
Jobswell Road
Carmarthen
United Kingdom
SA31 3BB

Study participating centre
Royal Devon & Exeter NHS Foundation Trust
Barrack Rd
Exeter
United Kingdom
EX2 5DW

Study participating centre
Tameside and Glossop Integrated Care NHS Foundation Trust
Fountain St
Ashton-Under-Lyne
United Kingdom
OL6 9RW

Study participating centre
Blackpool Teaching Hospitals NHS Foundation Trust
Whinney Heys Rd
Blackpool
United Kingdom
FY3 8NR

Study participating centre
Hampshire Hospitals NHS Foundation Trust
Aldermaston Rd

Basington
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RG24 9NA

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Calow
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S44 5BL

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Steeton Keighley
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BD20 6TD

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Blackshaw Rd
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SW17 0QT

Study participating centre
Nottingham University Hospitals NHS Trust
Derby Rd
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NG7 2UH

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North Tees and Hartlepool NHS Foundation Trust
Holdforth Rd
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TS24 9AH

Study participating centre
Bradford Teaching Hospital NHS Foundation Trust
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Wrightington, Wigan and Leigh NHS Foundation Trust
The Elms
Wigan Lane
Wigan
United Kingdom
WN1 2NN

Study participating centre
Frimley Health NHS Foundation Trust (Wexham Park)
Portsmouth Road
Frimley
United Kingdom
GU16 7UJ

Study participating centre
St Helens and Knowsley Teaching Hospitals NHS Trust
Warrington Rd
Prescot
United Kingdom
L35 5DR

Study participating centre
The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust
Castle Lane East
Bournemouth
United Kingdom
BH7 7DW

Study participating centre
Royal Berkshire NHS Foundation Trust (Reading)
London Road
Reading

United Kingdom
RG1 5AN

Study participating centre
Bolton NHS Foundation Trust
Minerva Rd
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BL4 0JR

Study participating centre
The Royal Wolverhampton NHS Trust
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WV10 0QP

Study participating centre
North West Anglia NHS Foundation Trust
Bretton Gate
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Peterborough
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PE3 9GZ

Study participating centre
The Oxford University Hospitals NHS Foundation Trust
Headley Way
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United Kingdom
OX3 9DU

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
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NR4 7UY

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Study participating centre
Wirral University Teaching Hospital NHS Foundation Trust
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Study participating centre
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BN11 2DH

Study participating centre
Brighton & Sussex University Hospitals NHS Trust
Eastern Rd
Brighton
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BN2 5BE

Study participating centre
The Dudley Group NHS Foundation Trust
Russells Hall Hospital
Pensnett Rd
Dudley
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DY1 2HQ

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
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LS9 7TF

Study participating centre
East Suffolk and North Essex NHS Foundation Trust
Turner Road
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CO4 5JL

Study participating centre
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2 Eday Rd
Aberdeen
United Kingdom
AB15 6RE

Study participating centre
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Sponsor information

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research.governance@bristol.ac.uk

Sponsor type
University/education

Website
http://www.bristol.ac.uk/red/research-governance/

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name
Royal College of Surgeons of England

Alternative Name(s)
RCS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
The Association of Breast Surgeons

Funder Name
The NIHR Bristol Biomedical Research Centre Director's Fund

Results and Publications

Publication and dissemination plan
Results will be published and presented at national and international meetings and in a peer-reviewed journal.

Added 09/04/2020:
Primary outcome results publication: 07/2021
Results and PROMs publication: 30/12/2022

Intention to publish date
30/03/2023

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

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 article	protocol	26/01/2020	09/04/2020	Yes	No
HRA research summary			28/06/2023	No	No
Results article		16/05/2022	18/07/2023	Yes	No
Results article		01/02/2025	26/02/2025	Yes	No