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A study evaluating the safety and effectiveness of Fortiva mesh in immediate implant-based breast reconstruction

Submission date 13/01/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 14/01/2020	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 09/09/2022	**Condition category** Surgery	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Breast reconstruction is offered to patients having a mastectomy and can be done at the same operation (an immediate reconstruction) or at a later date (delayed reconstruction). Silicone implants are the most common way of reconstructing breasts in patients having immediate reconstruction. This is commonly done using a mesh. Meshes can be made from man-made material (synthetic mesh) or from human or animal tissue that has been treated (biological mesh). A pocket is created to hold the implant in place underneath the skin. The upper part of the pocket is often formed by lifting the pectoral (chest wall) muscle. The lower part of the implant is supported by a mesh. This is called a sub-pectoral reconstruction. Another alternative is to make the whole pocket from mesh and place this on top of the muscle, known as pre-pectoral reconstruction. This is a newer technique and is also being assessed in this study. Many new mesh products continue to be developed to try and improve the results of implant reconstructions. These products need to be assessed to ensure that they are safe and effective. The aim of this study is to monitor and collect information about a new mesh designed for breast reconstruction with implants.

Who can participate?

Women over the age of 18 undergoing mastectomy for invasive or pre-invasive breast cancer or risk reduction, who elect to undergo a sub-pectoral or pre-pectoral immediate implant-based reconstruction with mesh

What does the study involve?

Information about complications that occur as a result of the surgery is collected. The main way of measuring the safety of the mesh is the number of patients who need to have their implant removed because of a complication from the surgery. Details of complications after the surgery are collected at 3 months and 18 months. These are compared with results from a group of 2000 patients who have had breast reconstruction with mesh and implants. Patients and surgeons are asked for their feedback on the result of the operation.

What are the possible benefits and risks of participating?
There is no direct benefit from taking part. This study will provide important safety information for future patients. If the Fortiva mesh is shown to be as safe as other meshes there may be a cost saving for the NHS. There is a risk that the Fortiva mesh may lead to more problems or complications compared with other meshes. The researchers plan to stop and check this after the first 46 patients have been enrolled in the study to look at this. The surgeons taking part in this study must have shown that they have low complication rates from breast implant surgery in order to use the new mesh.

Where is the study run from?
1. Hampshire Hospitals NHS Foundation Trust (UK)
2. Brighton And Sussex University Hospitals NHS Trust (UK)
3. The Newcastle Upon Tyne Hospitals NHS Foundation Trust (UK)
4. Nottingham University Hospitals NHS Trust (UK)
5. Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust (UK)
6. Berkshire Healthcare NHS Foundation Trust (UK)
7. Barts Health NHS Trust (UK)
8. Royal Liverpool and Broadgreen University Hospitals NHS Trust (UK)
9. Manchester University NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2019 to September 2024

Who is funding the study?
1. Association of Breast Surgery (UK)
2. National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Helen Scott
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Contact information

Type(s)
Scientific

Contact name
Ms Helen Scott

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
261822

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 42171, IRAS 261822

Study information

Scientific Title
A Mesh SAfety Platform for Immediate Implant-based BReAst Reconstruction (MAP-BRA) - Project 1. A multicentre prospective cohort study to evaluate the safety and effectiveness of Fortiva porcine acellular dermal matrix in immediate implant-based breast reconstruction

Acronym
MAP-BRA -1

Study objectives
The purpose of this study is to monitor and collect information about a new mesh designed for breast reconstruction with implants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/07/2019, North West – Liverpool Central Research Ethics Committee (3rd Floor Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; Tel: +44 (0)207 104 8196; Email: nrescommittee.northwest-liverpoolcentral@nhs.net), ref: 19/NW/0352

Study design
Non-randomised; Both; Design type: Treatment, Surgery, Cohort study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
The study is a single-arm phase II prospective cohort study to assess the safety and efficacy of the FORTIVA surgical mesh in patients undergoing immediate implant-based breast reconstruction. The study will recruit women who have elected to undergo a breast construction using as surgical mesh. Instead of the normal practice of the surgeon using their own or their hospitals own choice of mesh the surgeon will use the FORTIVA surgical mesh for the procedure. The same mesh will be used on all patient enrolled on the study.

Each patient will be on study for a period of 18 months. The patients will be enrolled onto the trial after they have received the patient information sheet had time to discuss the options with their clinical care team and their friend and family and having provided written informed consent. The patient will then undergo their breast surgery (using the FORTIVA mesh), in-patient recovery and out-patient follow-up as per standard of care. Additional data compared to standard of care will be collected at these visits, including baseline characteristics, details of the operation, pain assessments and details of any complications. Patients will then be asked to attend for three additional study visits over and above the standard of care at 30 days, 3 months and 18 months post-surgery. At these visits, the team will collect information on pain and complications. All study visits will take place in the tertiary care centre and will be conducted by the direct clinical care of the patient supported by research nurses as required.

The study will also ask the surgeons performing the procedure to complete a surgical questionnaire for each patient. As the main aim of the study is to estimate an acceptable implant loss rate and not to make direct comparisons with other treatments. This Simon 2 stage design was chosen as a well-established methodology for Phase II study. The study will recruit to a maximum of 79 patients. An assessment will be done after 46 patients have reached their 3 months follow-up. Recruitment will continue only if 5 or fewer patients have had an implant loss. If ≥ 6 implant losses are observed, the study will stop due to an unacceptable implant loss rate. At the point of the final analysis, the mesh will be deemed safe and suitable for further investigation.

Direct comparisons and randomisation are very difficult in this setting as there is no standard of care mesh or surgical method for the procedures. Surgeons conduct operations based on their experience and clinical decision making. Therefore as a secondary outcome the researchers will make comparisons with the patients recruited into the iBRA study, a prospective cohort of 2000 patients undergoing IBBR at over 70 centres between 2014 and 2016. Here comparisons will be made on a matched basis to give some indication of a direct comparison of FORTIVA and other approaches. The researchers plan to recruit patients over a 36-month period from 10 experience surgical centres across the UK.

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
Fortiva surgical mesh

Primary outcome measure
The safety and effectiveness of Fortiva mesh in implant-based breast reconstruction measured by recording implant loss rate at 3 months

Secondary outcome measures
1. The safety and efficacy of Fortiva mesh in implant-based breast reconstruction measured by:
1.1. Implant loss rate at 18 months
1.2. Complications of implant-based breast reconstruction with Fortiva mesh at 3 months
1.3. Complications of implant-based breast reconstruction with Fortiva mesh at 18 months
2. Product handling and surgeon experience of using Fortiva in subpectoral and prepectoral reconstruction measured using a surgeon self-report feedback form

Overall study start date
01/07/2019

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. Women over the age of 18 undergoing mastectomy for invasive or pre-invasive breast cancer or risk reduction
2. Elect to undergo a sub-pectoral or pre-pectoral immediate implant-based reconstruction with mesh

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 79; UK Sample Size: 79

Key exclusion criteria
Patients undergoing:
1. Revisional surgery

2. Delayed breast reconstruction
3. Previous breast or mantle radiotherapy
4. Patients who are allergic to pork or unwilling to have a porcine product
5. Patients unable or unwilling to give informed consent
6. Patients considered by their surgeon to be unsuitable for mesh reconstruction
7. Patients who currently smoke cigarettes or e-cigarettes
8. Patients with a BMI of 35 or above
9. Patients in whom it is anticipated that an implant volume of greater than 500cc will be required

Date of first enrolment
01/02/2020

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hampshire Hospitals NHS Foundation Trust
Aldermaston Road
Basingstoke
United Kingdom
RG24 9NA

Study participating centre
Brighton And Sussex University Hospitals NHS Trust
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
The Newcastle Upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton

Newcastle-upon-Tyne
United Kingdom
NE7 7DN

Study participating centre
Nottingham University Hospitals NHS Trust
Trust Headquarters
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Berkshire Healthcare NHS Foundation Trust
Fitzwilliam House
Skimped Hill Lane
Bracknell
United Kingdom
RG12 1BQ

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
Whitechapel
London
United Kingdom
E1 1BB

Study participating centre
Royal Liverpool and Broadgreen University Hospitals NHS Trust
Royal Liverpool University Hospital
Prescot Street

Liverpool
United Kingdom
L7 8XP

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Royal Liverpool and Broadgreen University Hospital NHS Trust

Sponsor details
c/o Debbie Atkinson
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United Kingdom
L7 8XP
+44 (0)1517063702
RGT@rlbuht.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.rlbuht.nhs.uk/Pages/RoyalHome.aspx

ROR
https://ror.org/009sa0g06

Funder(s)

Funder type
Government

Funder Name

Association of Breast Surgery

Alternative Name(s)
British Association of Surgical Oncology, ABS, BASO

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
National Institute for Health Research (NIHR) (UK)

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

Publication and dissemination plan
1. Study protocol not currently publicly available, please contact mapbra@liverpool.ac.uk for access to these documents
2. Peer-reviewed scientific journals
3. Conference presentation
4. Publication on website

Intention to publish date
31/03/2025

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 file	version 4.0	15/06/2021	17/08/2022	No	No
HRA research summary			28/06/2023	No	No