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A trial evaluating outcomes of immediate implant-based breast reconstruction using an acellular dermal matrix (ADM) (POBRAD trial)

Submission date 13/02/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 04/03/2013	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 30/01/2020	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-using-sheet-of-tissue-improve-breast-reconstruction-surgery-pobrad?

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Pobrad trial ref.11/LO/0336. 15th August2011, version 2.1

Study information

Scientific Title

Prospective, open-label trial evaluating Outcomes of immediate implant-based Breast Reconstruction using an Acellular Dermal matrix (ADM) (POBRAD trial)

Acronym
POBRAD

Study objectives
To date there have been a number of retrospective cohorts and case series reporting on outcomes following breast reconstruction using the porcine derived, non-crossed- linked surgical acellular dermal matrix Strattice (LifeCell , Branchburg, NJ) .

An alternative ADM is SurgiMend PRS, (TEI Bioscience Inc. Boston, MA), which is derived from foetal, bovine dermis enriched in type III collagen from which all cellular components have been removed, leaving a structurally intact and biochemically inert extracellular matrix made of elastin, collagen and glycoprotein components.matrix. It is believed to act as a scaffold allowing in-growth and regeneration of tissue following implantation and adding structural support and additional soft tissue cover.

The product is CE marked with an established safety record and indicated as an adjunct in a number of surgical procedures including breast reconstruction. As yet there is no prospective data on ADM use in breast reconstruction to validate clinical efficacy, complication rates and cost-benefit. This study is intended to provide robust, prospective clinically validated outcomes for the use of ADMs (SurgiMend PRS) as an adjunct in implant breast reconstruction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London-Bentham Research Ethics Committee London East, REC approval: 05/05/2011, ref: 11/LO /0336

Study design
Prospective open label non-randomised longitudinal observational study

Primary study design
Observational

Study type(s)
Treatment

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

Interventions
The POBRAD study aims to prospectively evaluate the complication rate, clinical and cosmetic outcome together with the cost-benefit analysis of the use of an acellular dermal matrix (ADM) for immediate implant based breast reconstruction in a population of newly diagnosed breast cancer patients.

Patients will be assessed for mastectomy-site complication rate, implant related complication rate and return to the theatre rate at post-operative, 1, 3 and 12 months post surgery.

Details of secondary sponsor:
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Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Mastectomy-site complication rate
2. Implant-related complication rate
3. Return to theatre rate

Measured 1, 3 and 12 months post surgery

Key secondary outcome(s))
1. Cosmetic outcome
2. Patient reported outcome
3. Cost-benefit analysis

Completion date
31/07/2012

Eligibility

Key inclusion criteria
1. Any person older than 18 years of age meeting the inclusion criteria are eligible to the study
2. All post-mastectomy patients undergoing immediate implant-based, breast reconstruction requiring lower pole cover

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Significant co-morbidities
2. Body mass index (BMI) >40
3. Locally advanced and/ or inflammatory breast cancer
4. Patients unable to provide informed consent to participate in trial

Date of first enrolment
20/07/2011

Date of final enrolment
31/07/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guy's and St Thomas' Hospitals
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
King's College of London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Industry

Funder Name
TEI Biosciences Inc. Boston, MA (USA) - Educational grant

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2013	30/01/2020	Yes	No