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

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

## Primary study design
Observational

## Study design
Prospective open label non-randomised longitudinal observational study

## 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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Email:karen.ignatian@gstt.nhs.uk
Website: http://www.guysandstthomas.nhs.uk

### 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 |