

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/03/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/01/2020	Condition category Cancer	<input type="checkbox"/> 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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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:

Guy's and St. Thomas' NHS Foundation Trust

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Tel: 02071885736

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Website: <http://www.guysandstthomas.nhs.uk>

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Mastectomy-site complication rate
2. Implant-related complication rate
3. Return to theatre rate

Measured 1, 3 and 12 months post surgery

Secondary outcome measures

1. Cosmetic outcome
2. Patient reported outcome
3. Cost-benefit analysis

Overall study start date

20/07/2011

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

40

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**

England

United Kingdom

Study participating centre

Guy's and St Thomas' Hospitals

London

United Kingdom

SE1 9RT

Sponsor information

Organisation

King's College of London (UK)

Sponsor details

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michael.douek@kcl.ac.uk

Sponsor type

University/education

Website

<http://www.kcl.ac.uk>

ROR

<https://ror.org/0220mzb33>

Funder(s)**Funder type**

Industry

Funder Name

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

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**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?
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[Results article](#)

results

01/11/2013

30/01/2020

Yes

No