# Mesh vs anterior repair surgery for vaginal prolapse

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
29/04/2008	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
24/06/2008	Completed	Results
Last Edited	Condition category	Individual participant data
13/06/2016	Urological and Genital Diseases	<ul><li>Record updated in last year</li></ul>

## Plain English summary of protocol

Not provided at time of registration

# 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

Project 032

# Study information

#### Scientific Title

Mesh vs anterior repair surgery for vaginal prolapse

#### Acronym

**MARS** 

#### **Study objectives**

If there is 15% statistical difference between the 2 techniques, we shall be able to tell the gynaecological community as to which one is better. There is a lack of good quality evidence to assess the two surgical techniques. Most of the data are from retrospective studies. A well designed randomised control study is desperately needed.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

South East Research Ethics Committee, ref: 07/H1102/95

#### Study design

Single-blind randomised controlled trial

#### Primary study design

Interventional

## Secondary study design

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

Genital prolapse

#### **Interventions**

Anteror fascial repair vs anterior mesh repair

#### Intervention Type

Other

#### **Phase**

**Not Specified** 

#### Primary outcome measure

Anatomical recurrence rate assessed using the Pelvic Organ Prolapse Quantification (POPQ) scores, assessed immediately after surgery and then 6 weeks, 6 months, 1 and 2 years post-operation.

#### Secondary outcome measures

- 1. Operating time
- 2. Blood loss
- 3. Peri-operative complications
- 4. Hospital stay
- 5. Time to recovery to normal life
- 6. Long-term complications (including mesh erosion). Duration of follow-up: 24 months
- 7. Bladder and sexual function at 6, 12 and 24 months
- 8. Quality of life, assessed using the EuroQol questionnaire and the Sheffield Prolapse Symptoms Questionnaire at 6, 12 and 24 months
- 9. Patient satisfaction, assessed at 6, 12 and 24 months
- 10. Pain score, assessed daily up to 7 days post-operation

#### Overall study start date

01/12/2007

#### Completion date

01/11/2010

# Eligibility

#### Key inclusion criteria

- 1. Women with symptomatic anterior vaginal wall prolapse needing surgery
- 2. Age: No age limits

#### Participant type(s)

**Patient** 

#### Age group

All

#### Sex

Female

## Target number of participants

250

#### Kev exclusion criteria

- 1. Contraindication to mesh repair surgery: unstable diabetes, long term high dose steroids, prosthetic heart valve, marked immunosuppression
- 2. Connective tissue disorders (Ehler-Danlos or Marfan's)
- 3. Inability to give informed consent

#### Date of first enrolment

01/12/2007

## Date of final enrolment

01/11/2010

# **Locations**

# Countries of recruitment

England

**United Kingdom** 

# Study participating centre Benenden Hospital Trust

Kent United Kingdom TN17 4AX

# Sponsor information

#### Organisation

Benenden Hospital Trust (UK)

#### Sponsor details

c/o Ken Hesketh Goddard's Green Road Benenden Kent United Kingdom TN17 4 AX

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.benenden.org.uk

#### **ROR**

https://ror.org/01bcp3a67

# Funder(s)

# Funder type

Hospital/treatment centre

### Funder Name

Benenden Hospital (UK)

# **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