Mesh vs anterior repair surgery for vaginal prolapse

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Mohamed Hefni

Contact details

Benenden Hospital Trust Goddards Green Road Benenden Kent United Kingdom TN17 4AX

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mhefni@benenden.org.uk

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

All

Sex

Female

Key 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

United Kingdom

England

Study participating centre

Benenden Hospital Trust

Kent United Kingdom TN17 4AX

Sponsor information

Organisation

Benenden Hospital Trust (UK)

ROR

https://ror.org/01bcp3a67

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Benenden Hospital (UK)

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?

Participant information sheet
Participant information sheet
11/11/2025 No Yes