ISRCTN69747860 https://doi.org/10.1186/ISRCTN69747860

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	**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

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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

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
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