

Abdominal versus vaginal surgery in the management of post hysterectomy vault prolapse: a randomised controlled study

Submission date 30/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 30/09/2005	Overall study status Completed	☐ Protocol
Last Edited 18/10/2017	Condition category Urological and Genital Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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

Protocol serial number
N0236102638

Study information

Scientific Title

Abdominal versus vaginal surgery in the management of post hysterectomy vault prolapse: a randomised controlled study

Study objectives

To determine the advantages and disadvantages of an abdominal or vaginal approach to correct vault prolapse/enterocele by conducting a prospective randomised controlled pilot trial comparing the abdominal sacrocolpopexy with mesh interposition and the vaginal bilateral iliococcygeal hitch

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Urological and Genital Diseases: Prolapse

Interventions

Randomised controlled trial

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Primary end point is the incidence of recurrence (Grade 2 prolapse) at 12 months post op.

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/09/2005

Eligibility

Key inclusion criteria

20 in total, 10 controls

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Uterus insitu, severe chronic medical illnesses, clotting or bleeding disorders, asymptomatic prolapse, morbid obesity.

Date of first enrolment

01/09/2001

Date of final enrolment

30/09/2005

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Gynaecology Department

London

United Kingdom

SW17 0QT

Sponsor information**Organisation**

Department of Health

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

St George's Healthcare NHS Trust (UK) No External Funding

Funder Name

NHS R&D Support Funding (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration