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

Submission date	Recruitment status	[_] Prospectively registered
30/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/10/2017	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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

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
Urological and Genital Diseases: Prolapse

Interventions
Randomised controlled trial

Intervention Type
Other

Phase
Not Specified

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2001

Completion date
30/09/2005

Eligibility

Key inclusion criteria
20 in total, 10 controls

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
20

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
England

United Kingdom

Study participating centre

Gynaecology Department
London
United Kingdom
SW17 0QT

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

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

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