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A randomised trial of open versus laparoscopic colposuspension for genuine stress incontinence

Submission date	Recruitment status	[_] Prospectively registered
25/10/2000	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/10/2000	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/07/2007	Urological and Genital Diseases	

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
G9721060

Study information

Scientific Title

Acronym
MRC COLPO Trial

Study objectives
To compare the cure rates in the two intervention groups. Additionally the two procedures will be compared in terms of perioperative morbidity, recovery time, incidence of postoperative voiding dysfunction, de novo detrusor instability and health economic costs to NHS and patient.

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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Stress incontinence

Interventions
The interventions under study will be open or laparoscopic colposuspension.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Primary Outcomes: complete cure of stress incontinence at 24 and 48 months. Symptom improvement classified as: Complete (have never leaked since surgery and no leakage objectively demonstrated),
Acceptable Improvement (matched patient expectations), Inadequate Improvement, No improvement, Worse. Levels of significant operative morbidity.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/1999

Completion date
28/02/2006

Eligibility

Key inclusion criteria
1. Any woman for whom a decision has been made to perform a colposuspension for cystometrically proven genuine stress incontinence.
2. Women who have had an anterior colporrhaphy would be eligible as it is considered that their inclusion is pragmatic reflecting everyday practice.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
290

Key exclusion criteria
1. Women in whom bladder neck surgery is contraindicated;
2. Women with detrusor instability.
3. Women who have had previous retropubic bladder neck surgery (colposuspension or sling procedure) or sacrocolpopexy.
4. Women who are unhappy to be randomised to laparoscopic colposuspension.
5. Women considered too obese for open colposuspension. (Laparoscopic colposuspension is only to be available as part of the trial.)

Date of first enrolment
01/03/1999

Date of final enrolment

28/02/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Unit of Obstetrics & Gynaecology Reproductive Healthcare
Manchester
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Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results:	01/09/2006		Yes	No