

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

Submission date

25/10/2000

Recruitment status

No longer recruiting

Registration date

25/10/2000

Overall study status

Completed

Last Edited

18/07/2007

Condition category

Urological and Genital Diseases

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

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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