

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

<b>Submission date</b> 25/10/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/10/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/07/2007	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Henry C Kitchener

### Contact details

Academic Unit of Obstetrics & Gynaecology Reproductive Healthcare

University of Manchester

St Mary's Hospital

Whitworth Park

Manchester

United Kingdom

M13 0JH

+44 (0)161 276 6646

henry.kitchener@cmmc.nhs.uk

## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Treatment

**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(s)**

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.

**Key secondary outcome(s)**

Not provided at time of registration

**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

## Healthy volunteers allowed

No

## Age group

Not Specified

## Sex

Not Specified

## 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

United Kingdom

England

## Study participating centre

**Academic Unit of Obstetrics & Gynaecology Reproductive Healthcare**

Manchester

United Kingdom

M13 0JH

# Sponsor information

## Organisation

Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

# Results and Publications

## 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?
<a href="#">Results article</a>	Results:	01/09/2006		Yes	No