

Laparoscopic treatment for female urinary incontinence

Submission date

23/01/2004

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

23/01/2004

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

24/10/2019

Condition category

Urological and Genital Diseases

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

F0004

Study information

Scientific Title

Laparoscopic treatment for female urinary incontinence

Study objectives

A Colposuspension procedure is one of the most effective operations undertaken to cure female urinary incontinence. Some gynaecologists believe that a laparoscopically performed Colposuspension may be superior to traditional open Colposuspension in terms of recovery time and cost effectiveness. However, there has never been a formal evaluation of the new procedure and the additional equipment costs and additional operative time required for a laparoscopic approach have never been justified. We plan to assess the value of laparoscopic Colposuspension in a prospective randomised controlled trial. We also aim to assess the value of day ward post-operative care in of catheterised patients in a randomised controlled trial since the benefits of shorter recovery time for the laparoscopic procedure would have little effect if patients were still required to stay in hospital catheterised until normal voiding was resumed.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Incontinence

Interventions

Laparoscopically performed Colposuspension vs. open Colposuspension procedure

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Assessment of outpatient or day ward post-operative care will include
 - 1.1. Urinary tract infection rates
 - 1.2. Rates of catheter problems such as kinking or blocking
 - 1.3. Patient satisfaction.
2. The outcome variables of interest are
 - 2.1. Surgical success rates
 - 2.2. Infection rates
 - 2.3. Intra-operative blood loss
 - 2.4. Post-operative pyrexia
 - 2.5. Length of stay
 - 2.6. Estimated financial costings

Key secondary outcome(s)

Not provided at time of registration

Completion date

28/02/1996

Eligibility

Key inclusion criteria

Women with urinary incontinence

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

03/01/1994

Date of final enrolment

28/02/1996

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Yorkshire Health

Leeds

United Kingdom

LS2 9NS

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration