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Laparoscopic treatment for female urinary incontinence

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/10/2019	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

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

Study design
Randomised controlled trial

Primary study design
Interventional

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