Randomised comparison of intermittent urethral and indwelling suprapubic catheterisation in the management of voiding after urogynaecological surgery

Submission date	Recruitment status No longer recruiting	Prospectively registered		
28/05/2009		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
09/07/2009	Completed	[X] Results		
Last Edited 01/05/2012	Condition category Urological and Genital Diseases	Individual participant data		

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 N/A

Study information

Scientific Title

Intermittent urethral versus indwelling suprapubic catheterisation in the management of voiding after urogynaecological surgery: a randomised single centre controlled trial

Study objectives

The aim of this study was to investigate the hypothesis that intermittent catheterisation (IC) is associated with a more rapid return to normal micturition following urogynaecological surgery by undertaking a randomised comparison of IC with suprapubic catheterisation in women undergoing surgery for urodynamic stress incontinence or utero-vaginal prolapse.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Newcastle and N. Tyneside Local Research Ethics Committees approved on the 20th January 2004 (ref: 2003/155)

Study design

Single centre randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Urodynamic stress incontinence, utero-vaginal prolapse

Interventions

All women electively admitted for surgery for urodynamic stress incontinence or pelvic organ prolapse were approached with a view to randomisation. A trial information leaflet was provided and those agreeing to participate completed a trial consent form in addition to their surgical consent. They were randomised into one of two groups using opaque sealed envelopes, opened prior to surgery by the consenting surgeon. No blinding of patient, surgeon, nurses nor outcomes assessor was feasible. The two randomisation groups were as follow:

Group 1: bladder drainage by a suprapubic catheter inserted in theatre. The catheter was left on free drainage for 48 hours post-operatively before commencing clamping

Group 2: catheterised intermittently post-operatively

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Length of hospital stay, measured from day of admission to day of discharge with a range of between 2 - 19 days.

Key secondary outcome(s))

- 1. The time to resume normal voiding (defined as voided volumes greater than 200 ml and post-void residual volumes consistently less than 100 ml), recorded within the time of the hospital stay
- 2. The number of episodes of urinary tract infection (UTI) (defined by catheter-specimen urine [CSU] or mid-stream urine [MSU] showing a single bacterium growing at a colony count greater than 100,000 colony forming units per ml), recorded within the time of the hospital stay
- 3. Patient experience of catheterisation as determined from a questionnaire given to patients at the end of their hospital stay, recorded within the time of the hospital stay, prior to discharge

Completion date

01/07/2004

Eligibility

Key inclusion criteria

All women electively admitted for surgery for urodynamic stress incontinence or pelvic organ prolapse. No age limits.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

Female

Key exclusion criteria

- 1. Women undergoing surgery where post-operative catheterisation is not routinely employed
- 2. Women requiring continuous post-operative bladder drainage, e.g. following repair of vesico-vaginal fistula, urethral diverticulectomy, augmentation cystoplasty and operative bladder injury

Date of first enrolment

01/04/2004

Date of final enrolment

01/07/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Directorate of Women's Services Newcastle upon Tyne United Kingdom NE1 4LP

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

ROR

https://ror.org/05p40t847

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (UK)

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?
Results article	results	01/10/2010	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes