

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

<b>Submission date</b> 28/05/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 09/07/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 01/05/2012	<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

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## Additional identifiers

## 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)

## **Primary study design**

Interventional

## **Study design**

Single centre randomised controlled trial

## **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?
<a href="#">Results article</a>	results	01/10/2010		Yes	No