

# 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

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### 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 measure**

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

### **Secondary outcome measures**

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

### **Overall study start date**

01/04/2004

### **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

### **Age group**

Other

### **Sex**

Female

### **Target number of participants**

Greater than 90 participants

### **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**

England

United Kingdom

**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)

**Sponsor details**

Royal Victoria Infirmary

Queen Victoria Road

Newcastle upon Tyne

England

United Kingdom

NE1 4LP

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.newcastle-hospitals.org.uk/services/index.aspx>

**ROR**

<https://ror.org/05p40t847>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded (UK)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## 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