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

Submission date
28/05/2009

Recruitment status
No longer recruiting

Registration date
09/07/2009

Overall study status
Completed

Last Edited
01/05/2012

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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?
Results article	results	01/10/2010		Yes	No