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Prospective randomised controlled trial of the usability and complications of two devices for suprapubic catheterisation in gynaecological surgery (TOSCA)

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
12/12/2019

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
N0158108047

Study information

Scientific Title
Prospective randomised controlled trial of the usability and complications of two devices for suprapubic catheterisation in gynaecological surgery (TOSCA)

Study objectives
To identify the most acceptable method of suprapubic catheterisation after colposuspension.

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
Surgery: Gynaecological

Interventions
All patients undergoing surgery for stress incontinence and extensive pelvic dissection which requires urinary catheterisation will be eligible to enter. Randomisation will be performed by a telephone link to a computer programme. Catheters will be inserted in theatre under general anaesthetic or spinal, irrespective of allocation. Procedures will be carried out by clinicians who have been trained in the insertion of both types of catheter. Data will be collected by questionnaire (three forms: one for the patient, one for the nursing staff, one for the surgeon [s]).

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
The primary endpoint will be patient acceptability.

Key secondary outcome(s)
The secondary endpoint will be complication rates for each catheter, the ease of performance of catheterisation, including any complications reported by the surgeon, and the ease of management of patients (while on catheter) as reported by the nursing staff.

Completion date
01/09/2003

Eligibility

Key inclusion criteria
All patients undergoing surgery for urine incontinence or extensive pelvic surgery requiring catheterisation.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Female

Key exclusion criteria
1. Lower abdominal scar
2. Bladder tumour
3. Allergy to natural rubber latex
4. Patient does not wish to participate

Date of first enrolment
01/09/2001

Date of final enrolment
01/09/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MO33
Stoke-on-Trent
United Kingdom
ST4 6QG

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
North Staffordshire Research and Development Consortium (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration