

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 12/12/2019	Condition category Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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