Suprapubic vs. transurethral catheterisartion in abdominal surgery: a randomized controlled trial

Published: 09-03-2009
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To identify the preferred method of bladder catheterisation in patients undergoing abdominal surgery (either vascular or gastro-intestinal surgery).

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON32702

Source
ToetsingOnline

Brief title
SPC vs. TUC in abdominal surgery

Condition

- Urinary tract signs and symptoms

Synonym
bladder catheterisation

Research involving
Human

Sponsors and support

Primary sponsor: IJssellandziekenhuis
Source(s) of monetary or material Support: IJsselland Ziekenhuis

Intervention

Keyword: abdominal surgery, catheterisation, urinary tract infection

Outcome measures

Primary outcome

Urinary tract infection

Secondary outcome

Bacterial load at time of catheter removal

Complications of the introduction technique of the catheter

Tolerance

Total costs

Study description

Background summary

Bladder catheterisation of patients undergoing abdominal surgery is mandatory, since epidural anesthesia causes a temporary dysfunction of the bladder. However, catheterisation leads to bacteriuria in a significant percentage of these patients (5 percent per day). There are two accepted methods for catheterisation: the suprapubis catheter (SPC) and the transurethral catheter (TUC). Although the SPC has the theoretical advantage of a lower rate of bacteriuria and might be better tolerated, the TUC is most commonly applied. Recent literature is unclear about the preferred method of catheterisation.

Study objective

To identify the preferred method of bladder catheterisation in patients undergoing abdominal surgery (either vascular or gastro-intestinal surgery).

Study design

Open label randomized controlled trial

Intervention

na

Study burden and risks

No additional risk for patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients undergoing abdominal surgery, either for gastro-intestinal or for vascular disease

Exclusion criteria

<18 years
urinary tact infection or incontinence at time of admission
incapable of giving informed consent

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-08-2009
Enrollment:	400
Type:	Actual

Medical products/devices used

Generic name:	catheter (CAD en SPC)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	09-03-2009
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL24394.101.08