When is the best moment to remove the urinary catheter after laparoscopic hysterectomy? A multicentre randomized controlled trial comparing direct versus delayed removal

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43898

Source
ToetsingOnline

Brief title
MUCH-study

Condition

- Other condition

Synonym
Urinary retention; inability to void

Health condition

Urinewegen (urineretentie en urineweginfectie)

Research involving
Human

Sponsors and support

Primary sponsor: Gynaecologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Laparoscopic hysterectomy, Urinary catheter

Outcome measures

Primary outcome

Urinary retention, defined as the inability to void (completely) 6 hours after

catheter removal.

Secondary outcome

Rate of re-catheterization

Urinary tract infection, based on clinical symptoms and urine sample after

catheter removal

Length of hospital stay

Moment of ambulation (defined as first time out of bed)

Presence of urine (objectified with bladder scan) after voiding before

discharge

Patient*s perspectives

Financial outcomes (cost-effectiveness)

Study description

Background summary

During laparoscopic hysterectomy (LH), an indwelling catheter is placed to avoid iatrogenic injuries to the bladder by keeping it empty. After surgery the catheter is in most hospitals left in place until the next day as direct removal of the catheter increases the risk of developing urinary retention. However no evidence based guideline about the best moment to remove the catheter exists and currently in most hospitals protocols are based on doctor*s experience. As prolonged stay of catheter is associated with delayed mobilisation, a higher risk of urinary tract infection and discomfort for the patients, it is important to investigate when the best moment to remove the catheter is.

Study objective

The aim of this study is to evaluate if direct removal of the urine catheter after an LH (total laparoscopic hysterectomy and laparoscopic supracervical hysterectomy) is associated with similar (or better) outcomes compared to catheter removal the next day after surgery (between 18 and 24 hours postoperative), which is the current treatment. In addition, we want to investigate patient*s experience on this subject.

Study design

Randomized Controlled trial, non-inferiority study.

Intervention

Treatment group: the patients in this group will have their catheter directly removed in the OR after LH.
Control group: the patients in the control group will have their catheter removed one day after the OR (between 18 and 24 hours postoperative, regular treatment)

Study burden and risks

In this study, no additional risk or burden is associated with participation. Patients will be monitored by the nurses in the same way as they are now. One urine sample will be taken from the patients to see if there are having a urinary tract infection. Patients will also be asked to fill in a questionnaire three times after surgery (6 hours; 24 hours and 1 week), about pain and their experience in the hospital.

Contacts

Public

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Older than 18 years
- Laparoscopic hysterectomy (with or without salpingo-oophorectomie)

Exclusion criteria

- Younger than 18 years old
- Concomitant procedures such as prolapse surgery, severe endometriose and/or bowel resection
- Preoperative known urinary voiding problems (incontinence)
- Preoperative known urinary tract infection
- Patients suffering from diseases potentially associated with inability to void (e.g. MS)
- A Gravid or postpartum hysterectomy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-05-2016
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	06-04-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-05-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL55504.058.15