

# When is the best moment to remove the urinary catheter after laparoscopic hysterectomy?

No registrations found.

|                              |                            |
|------------------------------|----------------------------|
| <b>Ethical review</b>        | Positive opinion           |
| <b>Status</b>                | Recruitment stopped        |
| <b>Health condition type</b> | -                          |
| <b>Study type</b>            | Observational non invasive |

## Summary

### ID

NL-OMON23293

### Source

NTR

### Brief title

MUCH study

### Health condition

Urinary catheter  
Laparoscopic hysterectomy  
Urinary retention  
Urinary tract infection

## Sponsors and support

**Primary sponsor:** none

**Source(s) of monetary or material Support:** none

## Intervention

## 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

„X VAS (OR+6 hours; OR+24 hours)

„X Satisfaction (OR+24 hours; OR+6weeks)

## **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 <sup>1</sup> 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.

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 delayed catheter removal after surgery, 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.

## Study objective

We hypothesize that 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 delayed catheter removal after surgery, which is the current treatment.

## Study design

6 hours after urinary catheter is removed

6 hours postoperative; 24 hours postoperative; 6 weeks postoperative

## Intervention

Group A (treatment group): the patients in this group will have their catheter directly removed in the OR after LH.

Group B (control group): the patients in the control group will have their catheter removed according to the regular protocol of the hospital (at least 6 hours in place).

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

Older than 18 years

Scheduled for LH for benign indication or low-grade malignancy (with or without salpingo-oophorectomie)

### Exclusion criteria

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:         | Observational non invasive  |
| Intervention model: | Parallel                    |
| Allocation:         | Randomized controlled trial |
| Masking:            | Open (masking not used)     |
| Control:            | Active                      |

### Recruitment

NL

|                           |                     |
|---------------------------|---------------------|
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 01-04-2016          |
| Enrollment:               | 160                 |
| Type:                     | Actual              |

## Ethics review

|                   |                  |
|-------------------|------------------|
| Positive opinion  |                  |
| Date:             | 01-04-2016       |
| Application type: | First submission |

## 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                       |
|----------|--------------------------|
| NTR-new  | NL5496                   |
| NTR-old  | NTR5818                  |
| Other    | NL55504.058.15 : P15.382 |

## Study results

### Summary results

N/A