

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

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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,...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23293

Bron

NTR

Verkorte titel

MUCH study

Aandoening

Urinary catheter

Laparoscopic hysterectomy

Urinary retention

Urinary tract infection

Ondersteuning

Primaire sponsor: none

Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 exists¹ 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.

Doel van het onderzoek

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.

Onderzoeksopzet

6 hours after urinary catheter is removed

6 hours postoperative; 24 hours postoperative; 6 weeks postoperative

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

Older than 18 years

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2016
Aantal proefpersonen:	160
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum: 01-04-2016

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5496
NTR-old	NTR5818
Ander register	NL55504.058.15 : P15.382

Resultaten

Samenvatting resultaten

N/A