

# One day versus three day suprapubic catheterisation after vaginal prolapse surgery: a randomized controlled trial.

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To determine the optimal moment to start bladder training after vaginal prolapse surgery with anterior colporrhaphy.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Bladder and bladder neck disorders (excl calculi)
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON30880

### Source

ToetsingOnline

### Brief title

Duration of catheterisation after prolapse surgery.

### Condition

- Bladder and bladder neck disorders (excl calculi)
- Uterine, pelvic and broad ligament disorders

### Synonym

vaginal prolapse

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Isala Klinieken

**Source(s) of monetary or material Support:** geen financiering aangevraagd

## Intervention

**Keyword:** catheter, colporrhaphy, prolapse

## Outcome measures

### Primary outcome

The primary outcome is the average duration of catheterisation, in postoperative days.

### Secondary outcome

The secondary outcomes are percentage of patients in whom the catheter can be removed after two days of succesful bladder training. The percentage of urinary tract infections, average duration of hospitalisation, percentage of ubretid use, residue volumes.

## Study description

### Background summary

In the Netherlands it is usual to prevent retention of the bladder with catheterisation after vaginal prolapse surgery with anterior colporrhaphy. The optimal duration of catheterisation however is unclear. The chance for uninary tract infection increases with a longer catheterisation. The chances for bladder distention and retention of urine increases with a shorter catheterisation. A randomized controlled trial already showed that earlier bladder training resluted in a shorter duration of catheterisation and less urinary tract infections. On the other hand a larger percentage of patients required recatheterisation. In our hospital bladder training is started three days after surgery. We hypothesize that starting the training at the first postoperative day will lead to a shorter duration of catherisation and less urinary tract infections. Another advantage of the suprapubic catheter that is used, is that recatheterisation is not necessary if the training failes.

### Study objective

To determine the optimal moment to start bladder training after vaginal

prolapse surgery with anterior colporrhaphy.

## Study design

A randomized controlled trial, with randomisation between starting bladder training one or three days postoperative.

## Intervention

The control group will start bladder training at the third day postoperative. The intervention group will start bladder training at the first postoperative day.

## Study burden and risks

Because the patients in the intervention group start their bladder training earlier, they have a greater chance of unsuccessful training after two days. However, for the training the catheter can stay in place, so they won't need recatheterisation and can resume the training at home. As soon as the training is successful they return to the hospital to have the catheter removed.

## Contacts

### Public

Isala Klinieken

Dokter van Heesweg 2  
8025 AB Zwolle  
Nederland

### Scientific

Isala Klinieken

Dokter van Heesweg 2  
8025 AB Zwolle  
Nederland

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Women that will have prolapse surgery including anterior colporrhaphy.

### Exclusion criteria

Not being able to understand the patient information

Not being able to give informed consent

Urinary tract infection on the day of surgery

Needing catheterisation before surgery

Contra-indications for suprapubic catheterisation

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	09-10-2007
Enrollment:	164
Type:	Actual

## Medical products/devices used

Generic name: Braun Cystofix suprapubic catheter  
Registration: Yes - CE intended use

## Ethics review

Approved WMO  
Date: 25-09-2007  
Application type: First submission  
Review commission: METC Isala Klinieken (Zwolle)

## 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	NL18635.075.07