

# A comparison of suprapubic and transurethral catheterization on postoperative urinary retention after vaginal prolapse repair.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON24810

### Source

NTR

### Brief title

CAD TRIAL

### Health condition

Urinary retention  
Cystocele repair  
Suprapubic catheterization  
Transurethral catheterization  
Vaginal prolapse surgery

## Sponsors and support

**Primary sponsor:** Deventer Ziekenhuis, Deventer, the Netherlands

**Source(s) of monetary or material Support:** Deventer Ziekenhuis, Deventer, the Netherlands

## Intervention

## Outcome measures

### Primary outcome

Urinary residual volume, defined as the percentage of patients with a residual volume more than 150 ml after spontaneous voidance the morning of the fourth postoperative day, following clamping (SP) or removing (TU) the catheter the evening before.

### Secondary outcome

1. Need for prolonged catheterization;
2. Length of hospital stay;
3. Number of patients with residual volumes exceeding 500 ml;
4. Need for recatheterization;
5. Rate of urinary tract infections;
6. Rate of complications.

## Study description

### Background summary

Objective:

To compare the effect of suprapubic catheterization with that of transurethral catheterization on residual urine volumes after vaginal prolapse surgery.

Methods:

Patients who underwent operative cystocele repair were randomized between a suprapubic catheter and a transurethral catheter. At the third postoperative day, the catheter in the suprapubic group was clamped and the catheter in the transurethral group was removed. Residual volumes after voiding were measured. Where the residual volume exceeded 150 ml, a prolonged stay or recatheterisation was effectuated. Urinary samples were taken before clamping or removing the catheter to measure the number of urinary tract infection. Need for prolonged catheterization, recatheterization and number of complications were registered.

### Study objective

We expected that the use of postoperative transurethral catheterization resulted in higher urinary retention rates in women after surgical correction of cystocele compared to suprapubic catheterization.

## Study design

1. Morning of the fourth postoperative day;
2. In case of first residual volume exceeding 150 ml: monitoring of residual volumes every 4 hours (suprapubic) and every 24 hours (transurethral);
3. End of catheterization;
4. 6 weeks after surgery.

## Intervention

1. Suprapubic catheterization after cystocele correction.
2. Transurethral catheterization after cystocele correction.

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

Women scheduled for surgical correction of cystocele (women undergoing prolapse surgery

without the correction of cystocele did not meet the inclusion criteria; patients who were planned for a procedure combining prolapse surgery with any technique for correction of incontinence, e.g. tension-free vaginal tape, were also not eligible).

## Exclusion criteria

1. History of urinary retention.
2. Urinary tract infection at the time of randomization.
3. History of urological disease or renal insufficiency.
4. Unability to speak and read the Dutch language.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2005
Enrollment:	116
Type:	Actual

## Ethics review

Positive opinion	
Date:	08-11-2008
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	NL683
NTR-old	NTR1528
Other	: 05.0534
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Study results

### Summary results

N/A