

# Catheter management bij symptomatische urineretentie na de bevalling.

No registrations found.

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

## Summary

### ID

NL-OMON27775

### Source

NTR

### Brief title

CAMPUR

### Health condition

urinary retention  
postpartum period  
catheter  
retention  
urinary

kraamtijd  
urine retentie  
niet kunnen plassen  
catheter

## Sponsors and support

**Primary sponsor:** Academic Medical Center, Amsterdam

**Source(s) of monetary or material Support:** Academic Medical Center, Amsterdam

## Intervention

## Outcome measures

### Primary outcome

Bladder related quality of life three months after randomization for symptomatic PUR (UDI-6 questionnaire)

### Secondary outcome

1. Development of a risk profile for overt postpartum urinary retention;
2. Prevalence of overt postpartum urinary retention (bladderscan);
3. The prevalence of clinical urinary tract infections due to different catheterization methods;
4. Cost effectiveness analysis for different treatments of overt PUR;
5. Patient preference for different methods of catheterization.

## Study description

### Background summary

Study Information:

CAMPUR: CATHeter Management and complications for symptomatic Postpartum Urinary Retention.

Objective:

Symptomatic postpartum urinary retention (PUR) is a common complication with a varying prevalence, from 0.5 - 18%. Woman who are diagnosed with symptomatic PUR are unable to void within 6 hours after the delivery or have clinical signs of a bladder retention within 6 hours. Besides the lack of standardized checks of postpartum urinary retention, agreement about definition, diagnostics and treatment is missing worldwide. Postpartum urinary retention often resolves quickly; most treated women can void spontaneously within a few days. However, some women have to learn intermittent self catheterization and continue this up to several months.

Untreated and unrecognized postpartum urinary retention can lead to serious complications and overdistension of the bladder can have long term effects.

In this study we compare two treatments for symptomatic postpartum urinary retention, indwelling catheters versus intermittent catheterization. Both of them are part of standard daily care and are used worldwide. We will evaluate which treatment makes PUR resolves

Study design:

Multicentre prospective randomised controlled trial.

Study population:

Women who deliver in the participating hospitals, vaginally and by caesarean section, 18 years and older and are unable to void within 6 hours postpartum.

Intervention:

Women who are diagnosed with overt postpartum urinary retention will be randomized between an indwelling catheter or intermittent bladder catheterization.

Outcome measures:

The main point of this trial is bladder related quality of life at 3 months after delivery. Secondary outcomes will be prevalence of urinary tract infections, creation of a risk profile and time to normal micturition with different treatments.

Power/data analysis:

A difference between both treatment groups of 3 points in the obstructive micturition domain (of the validated quality-of-life questionnaire) is considered to be a clinically relevant difference between both groups.

With a power of 90%,  $\alpha$  level of 0.05, and a standard deviation of 3.75, the calculated sample size necessary is 68 (34 in each group) using a two-sided two-sample t-test. Assuming a drop out of 15 %, we aim to include 84 women in this study

## **Study objective**

Symptomatic postpartum urinary retention (PUR) is a common complication with a varying prevalence, from 0.5 – 18%. Women who are diagnosed with symptomatic PUR are unable to void within 6 hours after the delivery or have clinical signs of a bladder retention within 6 hours. Besides the lack of standardized checks of postpartum urinary retention, agreement about definition, diagnostics and treatment is missing worldwide. Postpartum urinary retention often resolves quickly; most treated women can void spontaneously within a few days. However, some women have to learn intermittent self catheterization and continue this up to several months.

Untreated and unrecognized postpartum urinary retention can lead to serious complications and overdistension of the bladder can have long term effects.

In this study we compare two treatments for symptomatic postpartum urinary retention, indwelling catheters versus intermittent catheterization. Both of them are part of standard daily care and are used worldwide.

## **Study design**

Follow up until three months postpartum.

## **Intervention**

Randomization between indwelling catheterization and intermittent catheterization.

## **Contacts**

### **Public**

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## Eligibility criteria

### Inclusion criteria

1. Women who deliver in the participating hospitals;
2. Vaginally and by caesarean section;
3. 18 years and older;
4. Are unable to void within 6 hours postpartum.

### Exclusion criteria

1. Age < 18 years;
2. Insufficient knowledge or understanding of the Dutch language;
3. Congenital urinary tract abnormalities;
4. Pre-existent and treated urinary tract infection < 1 week before the delivery;
5. Patients with an indwelling catheter before delivery for parturition related reasons;
6. History of chronic neurological disease, including diabetic neuropathy.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-02-2011
Enrollment:	84
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	14-03-2011
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	NL2677
NTR-old	NTR2806
Other	MEC AMC : 10/187
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A