CAMPUR study: CAtheter Managment and diagnostics for symptomatic Postpartum Urinary Retention

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To compare which treatment (indwelling catheter versus intermittend catheterisation) has the best clinical effect in women with symptomatic PUR.

Ethical review	Approved WMO
Status	Pending
Health condition type	Postpartum and puerperal disorders
Study type	Interventional

Summary

ID

NL-OMON34494

Source
ToetsingOnline

Brief title
CAMPUR

Condition

- Postpartum and puerperal disorders
- Bladder and bladder neck disorders (excl calculi)

Synonym
not being able to void after giving birth, postpartum urinary retention

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Catheter, Postpartum, Retention, Urinary

Outcome measures

Primary outcome

The main point of this trial is bladder related quality of life at 3 months

after randomisation.

Secondary outcome

Secondary outcomes are prevalence of overt PUR, risk factors,

cost-effectiveness and patient preference.

Study description

Background summary

Postpartum urinary retention (PUR) is a common complication with a varying prevalence, from 0.5 - 18%. This great variety is mainly due to the use of different and non-standardized definitions.
Therefore, it seams plausible that there is a large discrepancy between the registered patients with PUR and the unknown and untreated. Postpartum urinary retention is most often selflimiting; patients are able to void spontaneous and empty their bladders completely within a few days. More than 50% of women with overt PUR recover within 24-48 hours, but a small part has to learn self catheterization for the duration of weeks to months.
Untreated and unrecognized postpartum urinary retention can lead to serious complications like urinary tract infections, pyelonefritis, urinary incontinence, renal failure and bladder rupture. This could have detrimental effects on the patient*s general health and quality of life. Accordance about definition and management of symptomatic urinary retention postpartum is missing worldwide; treatment is therefor in hands of the treating physician.

Study objective

To compare which treatment (indwelling catheter versus intermittend catheterisation) has the best clinical effect in women with symptomatic PUR.

Study design

A randomized controlled trial within a multi-centre prospective cohort study.

Intervention

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

Study burden and risks

Women in both treatment arms in this RCT will receive a non-experimental treatment. Current management is most often continuous catheterization, but also intermittent catheterization is part of standard care. This means there is no special burden associated with participation in this trial; sometimes it will mean that women can go home even sooner than now a days.
This trial do not involve specific risks for the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Women, 18 years and above, who are unable to void within six hours after vaginal or surgical delivery (symptomatic urinary retention)

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
7. Maternal fever (i.e. temperature >= 38.0 °C) due to a urinary tract infection, confirmed by a urine culture.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2010

Enrollment:	80
Type:	Anticipated

Medical products/devices used

Generic name:	Catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL33094.018.10