Catheter management bij symptomatische urineretentie na de bevalling.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27775

Bron
NTR

Verkorte titel
CAMPUR

Aandoening

urinary retention
postpartum period
catheter
retention
urinary

kraamtijd
urine retentie
niet kunnen plassen
catheter

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam

Overige ondersteuning: Academic Medical Center, Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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%, á 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

Doel van het onderzoek

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.

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Onderzoeksopzet

Follow up until three months postpartum.

Onderzoeksproduct en/of interventie

Randomization between indwelling catheterization and intermittent catheterization.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2011
Aantal proefpersonen:	84

Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-03-2011
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	NL2677
NTR-old	NTR2806
Ander register	MEC AMC : 10/187
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A