The COMPARE study: Prevalence and COMplications of Postpartum Asymptomatic urinary REtention.

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Postpartum urinary retention (PUR) is a complication with a varying prevalence, from 0.5 - 18%. For asymptomatic PUR, i.e. the ability to void but with a post residual volume (PVRV) of ≥150 ml, the estimation of prevalence is between 10-45...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21587

Bron
NTR

Verkorte titel
COMPARE

Aandoening

asymptomatic postpartum urinary retention

Ondersteuning

Primaire sponsor: AMC
Overige ondersteuning: AMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Micturition related quality of life after 3 months in women with asymptomatic postpartum urinary retention in a prospective cohort.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective:

The prevalence, complications and natural course of asymptomatic postpartum urinary retention.

Study design:

An observational prospective cohort study.

Study population:

Women who deliver vaginally in the participating hospitals of 18 years and older and have spontaneous micturition.

Intervention:

The volume of the first void after the delivery is measured in all women who deliver in the participating hospitals. After this, a non invasive abdominal bladderscan to measure the post void residual bladder volume (PVRV) will be done. Patients with an abnormal PVRV (≥ 150 ml) are asked to participate in the study; the natural course of asymptomatic postpartum urinary retention is followed by bladderscans. Patients with a normal PVRV are asked to participate in the control group.

Outcome measures:

Primary Objective: Micturition related quality of life after 3 months in women with asymptomatic postpartum urinary retention in a prospective cohort.

Secondary Objectives:

1. Prevalence of asymptomatic postpartum urinary retention;

2. Prevalence of urinary tract morbidity and care consumption in patients with asymptomatic postpartum urinary retention;

3. Identification of prognostic factors for asymptomatic postpartum urinary retention;

4. Costs related to asympyomatic abnormal post void residual volume.

Power/data analysis:

A difference of 8 points at the total score of the UDI-6 is considered to be clinically relevant. A standard deviation of 16 points is assumed to realize an effect-size of 0.5. To achieve a power of 90% for detecting a significant difference, ¦Á of 0.05, a total of 86 patients with asymptomatic urinary retention is needed when performing a 2-sided unpaired T-Test. Anticipating a drop-out of about 15%, we want to include 100 patients.

Doel van het onderzoek

Postpartum urinary retention (PUR) is a complication with a varying prevalence, from 0.5 - 18%. For asymptomatic PUR, i.e. the ability to void but with a post residual volume (PVRV) of ≥150 ml, the estimation of prevalence is between 10-45%. Untreated and unrecognized urinary retention can lead to distension of the detrusor muscle of the bladder. This serious complication can cause denervation, urinary tract infections, pyelonefritis, urinary dysfunction, renal failure and even bladder rupture.

In most hospitals, the residual bladder volume postpartum after spontaneous micturition is not measured and recorded. Therefore, little is known about the natural course and potential long term complications. The abcense of standard screening for abnormal post void residual volume means that morbidity due to inadequate bladder emptying are underdiagnosed.

Onderzoeksopzet

First measurement: After delivery;

Last measurement: Three months postpartum.

Onderzoeksproduct en/of interventie

Patients will be bladderscanned after spontaneous micturition. All patients with a post void residual volume (PVRV) > 150 ml will be included; they will receive measurements of the PVRV until it has normalized. These patients will fill out questionnaires and come back after three months.

Patients with a PVRV less than 150 ml are asked to participate in the control group and will fill out questionnaires.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All women of 18 years and older who deliver vaginally in the participating hospitals.

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. History of chronic neurological disease, including diabetic neuropathy;

6. Maternal fever (i.e. temperature ≥ 38.0 degrees C) due to a proved urinary tract infection;

7. Cesarean Section.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2011
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-10-2011
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	NL2971
NTR-old	NTR3118
Ander register	METC AMC : 2010-277
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A