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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21587

Source
Nationaal Trial Register

Brief title
COMPARE

Health condition

asymptomatic postpartum urinary retention

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: AMC

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Prevalence of asymptomatic postpartum urinary retention;

2. Prevalence of urinary tract morbidity and care consumption in patients with asymptomatic postpartum urinary retention compared to patients with a normal postvoid residual volume;

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

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

Study description

Background summary

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.

Study objective

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.

Study design

First measurement: After delivery;

Last measurement: Three months postpartum.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

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. 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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2011
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-10-2011
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	NL2971
NTR-old	NTR3118
Other	METC AMC : 2010-277
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A