Complications and prevalence of asymptomatic postpartum urinary retention

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This study will learn us about the prevalence of asymptomatic urinary retention postpartum, as well as the natural course and complications.

Ethical review	Approved WMO
Status	Pending
Health condition type	Postpartum and puerperal disorders
Study type	Observational non invasive

Summary

ID

NL-OMON36296

Source
ToetsingOnline

Brief title
COMPARE study

Condition

- Postpartum and puerperal disorders

Synonym
abnormal post void residual volume, inability to empty the bladder completely

Research involving
Human

Sponsors and support

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

Intervention

Keyword: asymptomatic, pospartum, retention, urinary

Outcome measures

Primary outcome

bladder 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. Natural course of bladder function in women with a PVRV of < 150 ml.

3. Prevalence of urinary tract infections in patients with asymptomatic

postpartum urinary retention.

4. Development of a risk profile for asymptomatic postpartum urinary retention.

5. Care consumption of patients with abnormal post void residual volume.

6. Micturition changes in patients with an abnormal and

patients with a normal post void residual volume.

Study description

Background summary

Postpartum urinary retention (PUR) is a common complication with a varying prevalence, from 0.5 - 18%; the prevalence of asymptomatic urinary retention is even higher, up to 45%. 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

This study will learn us about the prevalence of asymptomatic urinary retention postpartum, as well as the natural course and complications.

Study design

This is an observational study in a prospective cohort.

Study burden and risks

All women who participate in this study will return to the hospital three times for an abdominal bladderscan. They will return three months postpartum for the last check; in the period between they will fill out a care consumption diary and short questionnaires on different times.

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

All women of 18 years and older who deliver in the participating hospitals, vaginally, and have a post void residual volume of > 150 ml.

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 °C) due to a proved urinary tract infection

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

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

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	NL34461.018.10