BRAVO study: Bladderscan validation study for asymptomatic postpartum urinary retention

Published: 03-02-2012
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The reliability of the Bladderscan in the postpartum period and the prevalence of asymptomatic postpartum urinary retention.

Ethical review	Approved WMO
Status	Pending
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational invasive

Summary

ID

NL-OMON37324

Source
ToetsingOnline

Brief title
BRAVO study

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
Asymptomatic postpartum urinary retention; inadequate voiding after delivery

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: asymptomatic, Bladderscan, postpartum, urinary retention

Outcome measures

Primary outcome

Reliability of the Bladderscan

Secondary outcome

1. Prevalence of asymptomatic postpartum urinary retention

2. Risk profile for asymptomatic postpartum urinary retention

Study description

Background summary

Asymptomatic postpartum urinary retention, i.e. the inability to adequately empty the bladder after delivery, is a frequent condition. At this moment, the measurement of post void residual volume (PVRV) is not part of standard postpartum care.
The Bladderscan is a frequently used apparatus to measure the PVRV; small studies show it's reliability in the puerperium. Howeverd, these studies are very small and are underpowered.
This study will measure the reliabilty of the Bladderscan in the postpartum period; when the Bladderscan shows adequate reliabilty, it can become part of standard postpartum care.

Study objective

The reliability of the Bladderscan in the postpartum period and the prevalence of asymptomatic postpartum urinary retention.

Study design

An observational prospective study in an unselected cohort.

Study burden and risks

After vaginal delivery and spontaneous micturition, the PVRV will be measured

by Bladderscan and checked by catheterisation.
Bladderscanning is a short and non-invasive practice; although catheterisation is a invasive procedure, it is common practice on the delivery rooms and will create minimal burden for the patients. In addition, catheterisation will garantee complete emptying of the bladder.

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
after vaginal delivery

Exclusion criteria

women < 18 years
after cesarean section

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-02-2012
Enrollment:	1000
Type:	Anticipated

Medical products/devices used

Generic name:	Catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	03-02-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-12-2012
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL38262.060.11