URIKA, continuous ultrasound monitoring of urinary bladder filling in patients with urinary retention

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Primary Objective: Is the detection chance of the bladder influenced by the angle in which the ultrasound sensor is fixated? Secondary Objective Can the URIKA Bladder Monitor (UBM) be used to predict the point where the BladderScan reaches the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Observational non invasive

Summary

ID

NL-OMON43893

Source
ToetsingOnline

Brief title
URIKA: Continuous monitoring of urinary bladder filling in adults

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
Urinary retention

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Bladder, Medical device, Monitoring, Ultrasound

Outcome measures

Primary outcome

Best angle for fixating the ultrasound sensor, which give the most frequent

bladder filling results during measurement.

Secondary outcome

The sensitivity and specificity will be calculated for the UBM, how well the

threshold of 600 mL urine can be found in patients suffering POUR.

Study description

Background summary

Urinary incontinence (UI) and urinary retention are relatively common. Urinary retention after anaesthesia and surgery ranges between 5% and 70%.
In the previous study "URIKA, continuous ultrasound monitoring of urinary bladder filling in children with dysfunctional voiding: a pilot study" (METC nr: 15/050, NL51346.041.14) the URIKA bladder monitor is used for measuring the bladder diameter in children with dysfunctional voiding. The study with children is still ongoing.
Because we think that this bladder monitor could be an addition to the monitoring of adult patients, this study was designed. In this study, the focus lies on adults who suffer from postoperative urinary retention (POUR). Urinary retention occurs when the patient is unable to empty or sufficiently empty the bladder.
To increase the effectiveness of current clinical treatments, the URIKA device is developed. The URIKA device is an ultrasound sensor which is capable of measuring the distance between the anterior * and posterior wall of the bladder. It can measure the filling status of the bladder and can inform the patient when the bladder reaches its maximum capacity.

Study objective

Primary Objective: Is the detection chance of the bladder influenced by the angle in which the ultrasound sensor is fixated?

Secondary Objective Can the URIKA Bladder Monitor (UBM) be used to predict the point where the BladderScan reaches the threshold of 600 ml?

Study design

In this observational study (time: 10 months), 30 adult patients that underwent surgery with spinal anesthesia with the age of 18 years and up, will be measured real-time with the URIKA bladder monitoring device every 30 seconds (two times per minute) during their time on the recovery. The UBM will measure under a specific angle (pointing downwards into the pelvis). Three angles are used, therefore the group of 30 patients are divided into three groups:

* Patients 1-10 will be measured under an angulation of 10 degrees
* Patients 11-20 will be measured under an angulation of 20 degrees
* Patients 21-30 will be measured under an angulation of 30 degrees

The expected time frame of this study for the patients lies between 2-3 hours. At the start of the study, a BladderScan will be made, to determine the bladder volume. This scan is standard clinical care during observation at the recovery. Every following half hour an extra BladderScan will be made, until the endpoint of the study. The endpoint of the study is defined as the moment when the patient is ready to leave the recovery.

Study burden and risks

The patient is subjected to an ultrasound monitoring session of 2-3 hours. During this session the URIKA device will determine the urinary bladder diameter. As a reference volume measurements with the BladderScan will be made. There are no known risks associated with ultrasound monitoring or imaging when the ultrasound intensity is limited according to the current Food an Drug Administration regulations. The burden is relatively low for the patient.

Contacts

Public
Universitair Medisch Centrum Utrecht

Lundlaan 6
Utrecht 3584EA
NL
Scientific
Universitair Medisch Centrum Utrecht

Lundlaan 6

Utrecht 3584EA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patient is at least 18 years or older.
Patient underwent surgery with spinal anaesthesia.
Patient agree to participate in the study.
Patient is capable of understanding the procedure.

Exclusion criteria

Abdominal surgery (not possible to measure bladder via ultrasound).
Known pregnancy.
BMI > 25
Catheterized (urinary) patients

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-10-2015
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	URIKA Bladder monitor
Registration:	No

Ethics review

Approved WMO

Date:	02-09-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	06-07-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL53457.041.15