URIKA, continuous ultrasound monitoring of urinary bladder filling in children with dysfunctional voiding: a pilot study.

Published: 25-02-2015
Last updated: 21-04-2024

To determine the accuracy of the URIKA urinary bladder sensor in measuring the distance between the anterior - and posterior wall of the bladder and to determine the range in bladder diameters at which the child should be alarmed to void.

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-OMON44015

Source
ToetsingOnline

Brief title
URIKA sensor: Continuous monitoring of urinary bladder filling.

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
Dysfunctional Voiding

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

Main study parameter: measured distance (cm) between the anterior - and posterior wall of the urinary bladder, calculated by the software algorithm.

Secondary outcome

The secondary study endpoint of the study is the range in maximum urinary bladder diameters per individual and in the entire study population of 30 children with dysfunctional voiding. Furthermore, the Pearsons product - moment correlation coefficient will be estimated to determine the precision of the URIKA sensor, compared to traditional 2D ultrasound, for each angle. Also the age, gender, length and weight of the patients will be registered to establish a description of the study population.

Study description

Background summary

Urinary incontinence is defined as the involuntary or uncontrollable leakage of urine and is a common problem in children and adults. In the Netherlands, daytime incontinence for children older than four years is equals to 6-9% in girls and 7% in boys. Dysfunctional voiding is a subtype of the daytime voiding abnormalities, in which case the child habitually contracts the urethral sphincter during voiding. The child develops a wrong type of behaviour in which case they loss their urgency to go to the bathroom. They do not develop or even lose the ability to consciously recognize a full bladder, which will result in the involuntary leakage of urine when the bladder volume reaches its maximum. Dysfunctional voiding has a major impact on the lives of both the child and the family and it can result in a decrease in self-esteem, social isolation and teasing. As a result of the negative impact of urinary incontinence on the

child*s quality of life, it is important that these children receive clinical help and behavioural training. 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 and to prevent the child from wetting itself.

Study objective

To determine the accuracy of the URIKA urinary bladder sensor in measuring the distance between the anterior - and posterior wall of the bladder and to determine the range in bladder diameters at which the child should be alarmed to void.

Study design

Pilot study in 30 children with Dysfunctional Voiding.

Study burden and risks

The patient with dysfunctional voiding is subjected to an ultrasound monitoring session of 1.5 - 2 hours during a full cycle of urinary bladder filling. During this session, the URIKA device will determine the urinary bladder diameter during filling. As a reference, also multiple two-dimensional ultrasound images (Philips Medical Systems) will be made. The cycle of bladder filling is monitored four times (divided over one or several days). There are no known risks associated with ultrasound monitoring or imaging when the ultrasound intensity is limited according to the current Food and Drug Administration regulations. The burden is relatively low for the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Children with urinary incontinence, e.g. dysfunctional voiding.
- Children between the age of 6 and 12 years.
- Parents / Guardians agree to let their child participate in the study.
- Children are capable of understanding the procedure.

Exclusion criteria

- Subjects with symptoms of constipation.

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):	16-04-2015
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	URIKA
Registration:	No

Ethics review

Approved WMO Date:	25-02-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-09-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-09-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-02-2016
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	NL51346.041.14