NovioMini: continuous ultrasound monitoring of the urinary bladder in children during (video) urodynamics * a pilot study

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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-OMON45388

Source
ToetsingOnline

Brief title
NovioMini: continuous monitoring of the bladder during (video) urodynamic

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
urinary incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W,Novioscan BV. (Nijmegen, The Netherlands)

Intervention

Keyword: (Video) Urodynamics, Bladder, Monitoring, Ultrasound Sensor

Outcome measures

Primary outcome

The main study parameter is the full bladder detection rate of the NovioMini in children during (video) urodynamics. The full bladder detection is defined as the number of times a full bladder is detected by the NovioMini, divided by the number of bladder fillings during (V)UDO.

Secondary outcome

The second study parameter is the Pearson*s correlation coefficient r to determine if there is a linear correlation between the infused bladder volume during urodynamics and the measured anterior * posterior bladder dimension determined by the NovioMini Bladder Sensor. The final study parameters of this study are the maximum urinary bladder dimensions, maximum infused bladder volume, voided volume and residual volume (after voiding) for each child and for the range of these parameters for the entire study population of 30 children. Also, the time the child feels the urge to void is documented.

Finally, the following baseline characteristics will be collected: the (differential) diagnoses of urinary incontinence, gender, age, length, and weight and postural position (during (video)urodynamics) of the 30 children.

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. Urinary incontinence 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 NovioMini Bladder Monitor is developed. The NovioMini is an ultrasound sensor which is capable of measuring changes in the anterior * and posterior bladder over time. 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

In this study, the aim is to perform a clinical evaluation of the NovioMini in children during (video) urodynamics to examine the performance of the NovioMini over a wider range of bladder volumes and to determine if these is a relation between the anterior * posterior bladder dimension measured by the NovioMini and the infused bladder volume.

Study design

The study is designed as an observational, feasibility study in which children who are scheduled for a (video) urodynamic study are included. Parallel to the standardized clinical protocol of the (video) urodynamic study, the NovioMini Bladder Monitor will measure the anterior * posterior bladder dimensions every 30 sec to determine if there is a relation between this parameter and the infused bladder volume. The NovioMini will be positioned before the start of the filling phase and removed after the second voiding phase.

Study burden and risks

The patients who are included in this observational study are already scheduled for a (video) urodynamic study. During the (video) urodynamic study, the NovioMini Bladder Monitor is added as a minor supplement to the standardized clinical protocol. During the study, the NovioMini is positioned on the lower abdomen of the child and it will determine the urinary bladder dimension every 30 sec during the filling * and voiding phases. After the second voiding phase, the NovioMini is removed. 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 who are schedulded for (video) urodynamics
- Children between the ages of 6 to 12 years.
- Parents/ Guardians agree to let their child participate in the study.
- Children are capable of understanding the procedure.

Exclusion criteria

- Patients with breached skin, open wounds, sutures or major scar tissue in the suprapubic region.
- Patients with a suprapubic catheter.
- Patients with an urinary tract infection.

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):	28-03-2017
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	NovioMini Bladder Monitor
Registration:	No

Ethics review

Approved WMO

Date:	01-03-2017
Application type:	First submission
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	NL59567.041.17