NovioMini II: Clinical Evaluation of a Full Bladder Notification - a feasibility study -

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In this study, the aim is to perform a clinical evaluation of the NovioMini in children during behavioural bladder training to examine the performance of the NovioMini as a full-bladder-based notification system during natural bladder filling.

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-OMON44317

Source
ToetsingOnline

Brief title
NovioMini II: Clinical Evaluation of a Full Bladder Notification

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: Full Bladder, Notification, Training, Ultrasound sensor

Outcome measures

Primary outcome

The main study parameter of this study is the full bladder notification success-rate. The notification success-rate is stated as the number of times the NovioMini notified the child of a full bladder prior to micturition, divided by the micturition frequency (number of times the child voided while wearing the NovioMini).

Secondary outcome

The second study parameter of this study is the level of compliance of the patient to respond to the NovioMini notification(s). The level of compliance is stated as the number of times the patient alerts the urotherapist/researcher of the notification, divided by the number of times the NovioMini notified the child of a full bladder prior to micturition.

The final study parameters are (for each patient): micturition frequency, number of wet incidents (wet vs. dry), the bladder volumes and if urge symptoms occur, while wearing the NovioMini.

Finally, the (differential) diagnoses, gender, age, length, weight, BMI, the time of voiding, time the NovioMini goes off, total wear time of the NovioMini will be documented for the children in the study. Based on these parameters, a

description of the study population will be made.

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 behavioural bladder training to examine the performance of the NovioMini as a full-bladder-based notification system during natural bladder filling.

Study design

The study is designed as an observational, feasibility study in which children who are scheduled for a behavioural bladder training are included. Parallel to the standardized clinical protocol, the NovioMini Bladder Monitor will continuously measure the anterior * posterior bladder dimensions to determine when the bladder is full. When the NovioMini states that the filling status exceeds the pre-established full bladder threshold, the patient will be informed by a vibration signal of the device and a notification on the smartphone. When this occurs, the patient informs the urotherapist or researcher, same as for the wetting alarm which is used during the training. At the end of the day, the NovioMini will be removed and a couple of questions will be asked to determine the experiences of the patient with the device.

Study burden and risks

The patients who are included in this observational study are already scheduled

for a bladder training. During the training, 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 when the bladder is full. At the end of the training day, 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
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

* Children who are scheduled for an inpatient bladder training

* Children between the ages of 6 to 16 years.
* Children are capable of understanding the procedure.
* Parents / Guardians agree to let their child participate in the study.

Exclusion criteria

* Patients with breached skin, open wounds, sutures or major scar tissue in the suprapubic region.
* Patients with a suprapubic catheter (which prevents positioning the NovioMini properly)
* Patients with severe obesity (BMI > 95th percentile, according to age/gender)

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):	28-02-2018
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	NovioMini Bladder Monitor (in short: NovioMini)
Registration:	No

Ethics review

Approved WMO

Date:	15-01-2018

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	NL62895.041.17

Study results

Results posted: 30-04-2019

First publication
08-04-2019