SENS-U (TM) Bladder Sensor: continuous home monitoring of natural nocturnal bladder filling in children with nocturnal enuresis * an observational study

Published: 17-09-2018
Last updated: 11-04-2024

In this study, the aim is to perform a home based evaluation of the SENS-UTM Bladder Sensor during the night to examine the usability of the SENS-UTM for ambulatory care in children with nocturnal enuresis.

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-OMON46080

Source
ToetsingOnline

Brief title
SENS-U (TM): continuous monitoring of nocturnal bladder filling

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
Bedwetting, Nocturnal Enuresis

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W,Novioscan

Intervention

Keyword: ambulantory care, Enuresis, Full bladder, Ultrasound sensor

Outcome measures

Primary outcome

The main study parameter is the total number of natural nocturnal bladder filling cycles. This requires an increase in anterior-posterior bladder dimension over the time of one filling cycle.

Secondary outcome

The second study parameter is the position transition factor to determine the influence of sleep position on A-P bladder dimension. This transition factor is defined as the A-P dimension of the old position divided by the bladder dimension of the new position. The final study parameter is the theoretical notification success-rate. Other parameters which are documented are: A-P bladder dimensions (mm), voided volumes (mL), weight of diaper (mg), voiding times (hh:mm), body position, contact adhesive and skin and spout of gel. In addition, differential diagnosis, gender, age, length, weight, abdominal girth (cm) of the 15 children will be documented.

Study description

Background summary

Nocturnal enuresis is a common problem in 7-year olds; 5-10% suffer from this condition. Nocturnal enuresis is uncontrollable leakage of urine during the night. When there are no bladder bowel dysfunction symptoms present together with enuresis, it is called mono-symptomatic nocturnal enuresis. One of the

treatment options is alarm therapy. Currently, the wetting alarm is based on negative reinforcement to teach pelvic floor contraction when urine leaks. The SENS-U* Bladder Sensor is designed to help children stay dry during night and day, by providing a notification before the maximum bladder capacity is reached. Clinical results showed that the SENS-U* (formerly, NovioMini Bladder Monitor) was able to detect a full bladder during urodynamic research with a detection rate of at least 90%.

Study objective

In this study, the aim is to perform a home based evaluation of the SENS-UTM Bladder Sensor during the night to examine the usability of the SENS-UTM for ambulatory care in children with nocturnal enuresis.

Study design

This study is designed as an observational feasibility study, in which children are measured during the night at home. The SENS-UTM will measure anterior-posterior bladder dimension and sleep position. The SENS-UTM will be positioned before bed-time by the researcher. During the night, urine volume is collected in a measurement cup. The next morning, the SENS-UTM is removed by the researcher. Before and after measurement, the children*s sleep habits sub questionnaire is filled in.

Study burden and risks

There are no known risks associated with the use of the SENS-UTM. The burden is relatively low for the patient. They are asked to fill in the children*s sleep habit sub questionnaire before and after the measurement with their parents. The parents are also asked to fill in the voiding diary during the night.

Contacts

Public
Jeroen Bosch Ziekenhuis

Henri Dunantstraat 1
Den Bosch 5223
NL
Scientific
Jeroen Bosch Ziekenhuis

Henri Dunantstraat 1
Den Bosch 5223

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Monosymptomatic nocturnal enuresis
- age between 6 to 12 years (<12)
- permission of parents/guardians to let their child participate in the study
- capability of the child to understand the procedure

Exclusion criteria

- small bladder capacity : less than 65% of the expected bladder capacity
- breached skin, open wounds, sutures or major scar tissue in the suprabubic region
- nightly use of a (suprabubic) catheter

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):	11-10-2018
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	SENS-U (TM) Bladder Sensor
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-09-2018
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL66810.028.18