SENS-U: continuous ultrasound monitoring of the urinary bladder in adults during urodynamic studies – a pilot study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26879

Source
Nationaal Trial Register

Brief title
SENS-U

Health condition

Lower Urinary Tract Symptoms (LUTS)

Sponsors and support

Primary sponsor: CWZ Nijmegen
Source(s) of monetary or material Support: Novioscan B.V.

Intervention

Outcome measures

Primary outcome

Bladder filling by strongest desire to void (in mL) or so-called 'maximal bladder filling

capacity'
- Measured bij urodynamic studies (golden standard for this measurement) and the SENS-U bladder scan.
- Timepoint: on indication by patient. (reported by patient)

Secondary outcome

Residu after micturation (in mL)
- Measured by conventional bladder scan (standard for this measurement) and the SENS-U bladder scan
- Timepoint: after completion of micturation (reported by patient)

Study description

Background summary

Rationale: Urinary incontinence is defined as the involuntary or uncontrollable leakage of urine and is a common problem in children and adults. Daily urinary incontinence (UI) is reported in 9-39% of women over 60 and 2-11% in older men [1]. UI has a considerable social and economic impact on individuals and society. To potentially prevent UI from occurring, it would be beneficial to know when the bladder has reached or is close to its maximum capacity. A possible way to continuously measure bladder filling, is by using the SENS-U Bladder Sensor (SENS-U). The SENS-U is a wearable ultrasound sensor which is designed to measure the filling status of the bladder in children and inform the child when the bladder reaches its maximum capacity and subsequently prevent the child from wetting itself. Possibly the SENS-U can be used in a similar way to inform adult UI patients when their bladder reaches the maximum capacity and thereby prevent leakages. However, the anatomical position of the bladder in adults is lower than that in children, which possibly influences the performance of the SENS-U in adults.

Objective: In this study, the aim is to perform a clinical evaluation of the SENS-U in adults during an urodynamic study to examine the performance of the SENS-U over a wider range of bladder volumes and to determine if these is a relation between the anterior – posterior bladder dimension measured by the SENS-U and the infused bladder volume.
Study design: The study is designed as an observational, feasibility study in which subjects who are scheduled for an urodynamic study are included. Parallel to the standardized clinical protocol of the urodynamic study, the SENS-U 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 SENS-U will be positioned before the start of the filling phase and removed after the last voiding phase.

Study population: 40 subjects who are scheduled for an urodynamic study. Subjects should be ≥ 16 years old. Subjects are divided in 2 groups of 20, one group with Body Mass Index (BMI) ≤25 and one group with 25 1 cm is detected by the SENS-U once the bladder is full (i.e.

filled to its maximum capacity), divided by the number of bladder fillings during the urodynamic study. The second study parameter is the Spearman's correlation coefficient r_s to determine if there is a monotonic relation between the infused bladder volume during the urodynamic study and the measured anterior – posterior bladder dimension determined by the SENS-U. The final study parameters are the range in maximum urinary bladder dimensions, maximum infused bladder volume, voided volume and residual volume (after voiding) for each subject and for the entire study population. Also, the time the subject feels the urge to void and the volume after voiding is documented. Finally, the following baseline characteristics are reported: the (differential) diagnoses of urinary incontinence, gender, age, motherhood, length, weight, abdominal girths (circumferences at the height of the belly button and the hips), and postural position (during the urodynamic study).

Study objective

The main study parameter is the full bladder detection rate at the moment of maximum bladder capacity (urge feeling). The full bladder detection rate is defined as the number of times a full bladder is detected by the SENS-U (A-P bladder dimension > 1 cm) divided by the number of bladder fillings during the urodynamic study.

Study design

n.a.

Intervention

n.a.

Contacts

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Eligibility criteria

Inclusion criteria

Subject who are scheduled for an urodynamic study.
Subject must be older than (≥) 16 years of age.
Subject must have a body-mass-index (BMI) < 30.
For subjects between 16 and 18 years old, parents / guardians agree to let their child participate in the study.
Subjects are capable of understanding the procedure.

Exclusion criteria

Subjects with breached skin, open wounds, sutures or major scar tissue in the suprapubic region.
Subjects with a suprapubic catheter.
Subjects with a urinary tract infection (UTI).
Subjects who are pregnant.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-11-2020
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	12-10-2020
Application type:	First submission

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
NTR-new	NL9022
Other	CWZ Nijmegen and METC Nijmegen : Local code 072-2020, METC 2020-6901

Study results