Evaluation of the additional effect of continuous ultrasound bladder monitoring in urotherapy for children with functional daytime urinary incontinence. The SENS-U trial

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To evaluate cost effectiviness of the SENS-U (continuous ultrasonic bladder monitoring) in urotherapy for children with functional daytime urinary incontinence.

Ethical review	Approved WMO
Status	Recruitment started
Health condition type	Urinary tract signs and symptoms
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON56214

Source
ToetsingOnline

Brief title
The SENS U trial

Condition

- Urinary tract signs and symptoms

Synonym
Lower urinary tract symptoms/ functional urinary incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

- Medical device

Keyword: children, Functional urinary incontinence, SENS-U, urotherapy

Explanation

N.a.

Outcome measures

Primary outcome

Primary outcome is number of wetting accidents per week after 3 months of
urotherapy.

Secondary outcome

Secondary outcomes are long term outcomes,, subjective experiences, adherence,

voiding frequencies, post-void residuals and volume, uroflowmetry curves, and
quality of life and cost effectiviness defined by QUALY's.

Study description

Background summary

Functional urinary incontinence is a common condition with a prevalence of 10-20% in 7 year-old children. It is associated with an impaired QoL, lower self-esteem, and social stigmatization. Children rate *wetting their pants in class* repeatedly in the top 5 of most stressful life events.

First line treatment according to the International Children*s Continence Society (ICCS) is urotherapy. Urotherapy is a noninvasive, nonpharmacological treatment, defined as bladder re-education or rehabilitation aiming at correcting the filling and voiding function of the bladder-sphincter unit. Urotherapy combines education and demystification of lower urinary tract (dys)function, behavioral modification instructions, lifestyle advice regarding

fluid intake, voiding frequencies, registration of voided volumes and incontinence episodes, and support/encouragement to children and their parents. In urotherapy, tools like voiding diaries and wearable alarm systems are commonly used. They are intended to gain insight in voiding behavior and to teach children how to respond adequately to bladder filling and voiding signals.

A new wearable bladder sensor recently became available, the SENS-U. This is a small, wireless ultrasonic sensor, which continuously monitors bladder filling and alarms the child when it is time to void. The SENS-U may increase children*s awareness of the sensation of a full bladder. It can be personalized by adjusting the percentage of bladder filling at which it sends an alarm, based on the children*s own bladder capacity and voiding diary data. This teaches children which bladder sensation corresponds to a nearly full bladder. In current urotherapy, the bladder sensation that corresponds to a full bladder can only be explained by the urotherapist. Biofeedback on bladder filling with the SENS-U enables children to directly feel what the urotherapist means, thereby inducing less trial-and-error. This reduces the number of failing experiences. Furthermore, we expect steeper individual learning curves and more cost-effective urotherapy.

Study objective

To evaluate cost effectiviness of the SENS-U (continuous ultrasonic bladder monitoring) in urotherapy for children with functional daytime urinary incontinence.

Study design

Multicenter RCT comparing urotherapy alone, with SENS-U, and with sham device. Children are randomized per center. There are four participating centers.

Intervention

Urotherapy with the SENS-U. The SENS-U is a wearable ultrasound device that continuously measures bladder filling and gives an alarm at a preset bladder filling (e.g. 80% filling). The SENS-U provides biofeedback that teaches the child at which feeling of the bladder (e.g. the feeling corresponding with 80% filling) the child has to void.
The feeling of a device on the children*s belly could increase awareness of their bladder and might induce a placebo effect. Therefore, we include a placebo group, wearing a sham device that alerts independent of bladder filling at a set interval. The SHAM device resembles the traditional timer watch which is currently often used in urotherapy. Therefore it is not considered an extra burden for children to wear a SHAM device. The SHAM and accompanying instructions are identical to the SENS-U. The interval between alarms is

randomly chosen between 2 to 3 hours to appear realistic.

Study burden and risks

Urotherapy is care as usual which includes standard procedures like a voiding diary, frequency voiding chart (FVC) and uroflowmetry and residual measurement (PVR) and regular contact moments with the health care provider. This is not an extra burden for subjects. To monitor incontinence-related QOL and adherence, questionnaires are used at T0, T3 and T6. The SENS-U or SHAM are alarm devices without additional risks which might give discomfort or redness of the skin while wearing it. The SENS-U and sham device automatically register whether they are worn or not to measure adherence. The amount of questionnaires is limited and no intimate questions are asked.
All subjects might benefit from treatment with reduction in wetting accidents after treatment. The extent of reduction in wetting accidents or time to achieve response might be beneficial for those wearing an alarm device.

Contacts

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Trial sites

Trial sites in the Netherlands

Radboud Universitair Medisch Centrum
Target size: 44

Universitair Medisch Centrum Utrecht

Target size: 44

Isala
Target size: 44

Top voor kinderen BV
Target size: 44

Ziekenhuisvoorzieningen Gelderse Vallei
Target size: 44

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Children (2-11 years)

Inclusion criteria

• Age >= 6 years and < 16 years
• Presenting with functional daytime urinary incontinence according to previous definition (>= one episode a month , >= 3 months)
• Diagnosed with overactive bladder, dysfunctional voiding or underactive bladder with or without recurrent urinary tract infections according ICCS criteria/classification
• Eligible for urotherapy/ bladder training as the treatment of choice by the clinician
• No current urinary tract infection (UTI) at the start of the study

Exclusion criteria

• History of congenital urogenital anomalies except for successfully treated mild infravesical obstruction (meatal stenosis, mild urethral valves) < 3 months before inclusion
• History of neurological underlying disease
• Untreated or treated but persisting functional constipation according to Rome IV criteria at the start of the study < 6 months before inclusion.
• Recurrent culture proven UTI (less than 3 months before start of the study or not under control by prophylactic antibiotics)
• Previous urotherapy/ bladder training within 6 months of start of the study
• Adipositas preventing accurate measurement by the SENS-U as defined as a BMI

> 95th percentile according to age/gender.
• Skin problems in the suprapubic area that are incompatible with the SENS-U adhesive
• Developmental and intellectual disabilities or severe behavioural and social problems that are incompatible with protocolled urotherapy treatment based on the history and opinion of the clinician/ urotherapist.

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment started
Start date (anticipated):	10-03-2023
Enrollment:	219
Duration:	6 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	Medical device
Generic name:	SENS-U
Registration:	Yes - CE intended use

IPD sharing statement

Plan to share IPD: Undecided

Plan description

N.a.

Ethics review

Approved WMO Date:	04-01-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-11-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-04-2025
Application type:	Amendment
Review commission:	METC Oost-Nederland

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
ISRCTN	44345202
CCMO	NL78403.091.21
Research portal	NL-006150