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Evaluation of the SENS-U as an alarm intervention in the treatment of children with daytime urinary incontinence

Submission date 04/01/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 23/03/2022	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 31/12/2025	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Urotherapy is the first treatment of choice for functional daytime urinary incontinence (DUI) in children. Alarm therapy can be a part of urotherapy as it provides the child adequate feedback on wetting accidents. Current alarm systems notify either at a set interval or give a notification when wetting has already occurred to prompt the child to go to the toilet. These alarms do not teach the child the interpretation of the bladder sensation preceding wetting accidents. A new wearable bladder sensor, the SENS-U, recently became available. This is a small, wireless ultrasonic sensor, which continuously monitors bladder filling. The SENS-U is able to provide an alarm at the exact moment voiding is warranted. It facilitates the child to learn the sensation of bladder filling preceding voiding in an easier way, increasing the learning curve throughout treatment.

The aim of this multicenter single-blinded randomized controlled trial is to assess the additional effect of continuous ultrasound bladder monitoring in urotherapy for children with functional daytime urinary incontinence.

Who can participate?
Children aged 6 to 16 years old with functional daytime urinary incontinence.

What does the study involve?
Participants will be divided into three groups at random, with each participant having an equal chance of being in each group. Participants will receive either urotherapy only for 3 months, urotherapy for 3 months with 3 consecutive weeks using the SENS-U device, or urotherapy for 3 months with 3 consecutive weeks with the using a sham device.

What are the possible benefits and risks of participating?
By training, subjects might benefit from treatment by reduction in wetting accidents. Potential risks are discomfort or redness of the skin while wearing the device.

Where is the study run from?
Radboud UMC (Netherlands)

When is the study starting and how long is it expected to run for?
From June 2021 to June 2026

Who is funding the study?
ZonMw (Netherlands) and Novioscan (Netherlands)

Who is the main contact?
Eline van de Wetering, Eline.vandewetering@radboudumc.nl

Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
80-85200-98-21037

Study information

Scientific Title
The SENS-U trial: evaluation of the additional effect of continuous ultrasound bladder monitoring in urotherapy for children with functional daytime urinary incontinence

Acronym
SENS-U

Study objectives
Urotherapy combined with the SENS-U reduces the number of wetting accidents per week in children with functional daytime urinary incontinence

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/01/2022, METC Oost-Nederland (Philips van Leydenlaan 25, 6500 HB Nijmegen; +31 (0)24 3613154; commissiemensgebondenonderzoek@radboudumc.nl), ref: 2021-13134, NL number: NL78403.091.21

Study design
Multicenter interventional single-blinded randomized controlled trial

Primary study design

Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of children with functional daytime urinary incontinence

Interventions
Participants will be divided into 3 arms in a 1:1:1 fashion:
1. Urotherapy only (control group)
2. Urotherapy + SENS-U
3. Urotherapy + Sham-device (placebo)
Urotherapy will be given for 3 months. Children who are placed in the SENS-U or Sham-device arm will wear the device for 3 consecutive weeks during the 3 months of urotherapy treatment.

The SHAM-device has the exact same appearance as the SENS-U. However, it does not measure the filling state of the bladder. The SHAM-device is programmed to give an alarm at set time intervals. The device can best be compared to alarm interventions such as the timer watch.

Outcome parameters will be measured at baseline, after the end of 3-weeks intensive training with diary, after 3 months, and at 6 months after starting training.

Intervention Type
Device

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
SENS-U Sham-device (placebo)

Primary outcome(s)
Number of 'wetting accidents' per week measured by questionnaires at baseline and 3 months

Key secondary outcome(s))
1. Subjective improvement of LUTS according to parents using questionnaires at baseline, 3, and 6 months
2. Change in urinary incontinence during follow-up measured using the number of wetting accidents per week at 6 months
3. Change in frequency voiding chart parameters (average, minimum, maximum void volumes corrected for bladder capacity for age (EBC) measured using voiding charts at baseline, 3, and 6 months
4. Change in Quality of Life measured using questionnaires at baseline, 3, and 6 months
5. Cost-effectiveness measured using questionnaires set out to costs at 6 months
6. Magnitude of the placebo-effect measured using number of wetting accidents per week at baseline and 3 months

Completion date
08/06/2026

Eligibility

Key inclusion criteria
1. Aged between 6 and 15 years
2. Functional daytime urinary incontinence
3. Diagnosed with overactive bladder, dysfunctional voiding, or underactive bladder according to ICCS criteria
4. Eligible for urotherapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
15 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. History of congenital urogenital anomalies except for successfully treated mild infravesical obstruction
2. History of neurological underlying disease
3. History of botox treatment for lower urinary tract dysfunction (LUTD)
4. Untreated or treated but persisting functional constipation according to Rome IV criteria <6 months before inclusion
5. Recurrent culture-proven urinary tract infection (UTI) <3 months before inclusion or not controlled by prophylactic antibiotics
6. Previous urotherapy/bladder training <6 months before inclusion
7. Adipositas preventing accurate measurement by the SENS-U as defined as a BMI >95th percentile according to age/gender
8. Skin problems in suprapubic area that are incompatible with the SENS-U adhesive
9. Developmental and itellectual disabilities or severe behavioural and social problems that are incompatible with protocolled urotherapy treatment based on the history and on the opinion of the clinician/urotherapist

Date of first enrolment
01/02/2022

Date of final enrolment
01/04/2024

Locations

Countries of recruitment
Netherlands

Study participating centre
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Sponsor information

Organisation
Radboud University Nijmegen Medical Centre

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Research organisation

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Funder Name
Novioscan

Results and Publications

Individual participant data (IPD) sharing plan
Pseudonymized individual participant data is stored and analyzed in anDREA during the study. At the end of the study, all generated data will be stored in a proprietary format in the DANS EASY

repository. In order to reproduce the study findings and to help future users to understand and reuse the data, all changes made to the raw data, including analysis steps will be documented in a data management plan.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		13/08/2022	15/08/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 10.3		31/12/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes