An explorative, single-center, feasibility study to collect data for the continuous development of the TENA Bladder Sensor Algorithm in adults during urodynamics.

Published: 25-05-2022
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Primary objectiveTo collect data for the continuous development of an algorithm to determine the bladder filling status with the future TENA Bladder Sensor.Secondary objectiveTo document adverse events (AE) and device deficiencies (DD): namely AEs,...

Ethical review	Approved WMO
Status	Completed
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON51822

Source
ToetsingOnline

Brief title
Data collection for development of a bladder sensor during urodynamics.

Condition

- Urinary tract signs and symptoms

Synonym
Involuntary leakage of urine, Urgency

Research involving
Human

Sponsors and support

Primary sponsor: Essity Hygiene and Health AB

Source(s) of monetary or material Support: Essity Hygiene and Health AB

Intervention

Keyword: Bladder, Ultrasound, Urodynamics, Wearable

Outcome measures

Primary outcome

Primary endpoints

• Full bladder detection rate before urination.

Secondary outcome

Secondary endpoints

• Incidence of any AEs, DDs, ADEs, SAEs, SADEs and USADEs

Exploratory endpoints

• Minimum and maximum detectable bladder volume by TENA-PROTO2

• Relation between the bladder filling status measured by the TENA-PROTO2 and the infused bladder volume (ml) during the urodynamics

If there is a relation between the bladder filling status determined by the algorithm and the infused bladder volume:

(1) Full bladder detection rate (%) by future algorithm

(2) Theoretical notification rate (%), if relation is found

(3) Volume of the bladder (ml) by advanced algorithm

(4) Determine the residual urinal volume after voiding

Study description

Background summary

The future Bladder Sensor aims to prevent urinary incontinence in adult patients (>18 years) with spinal cord injury, spina bifida, post-surgery urinary retention, urge incontinence, overflow incontinence and who perform intermittent catherization. In this explorative feasibility study data from patients that match age, BMI and sex of the intended users will be collected with the second prototype of the Bladder Sensor.

Study objective

Primary objective

To collect data for the continuous development of an algorithm to determine the bladder filling status with the future TENA Bladder Sensor.

Secondary objective
To document adverse events (AE) and device deficiencies (DD): namely AEs, DD, Adverse Device Events (ADE), Severe Adverse Events (SAE), Severe Adverse Device effects (SADE) and Unanticipated Serious Adverse Device Effects (USADE).

Exploratory objectives
According to the primary objective, data will be used for continuous development of the algorithm in parallel to the study and beyond. First, data will be used to determine minimum and maximum detectable bladder volume by TENA-PROTO2 and if there is a relation between the bladder filling status determined by the future algorithm and the infused bladder volume during urodynamics. Second, if there is a relation between the bladder filling status determined by the algorithm and the infused bladder volume, the following exploratory objectives will be investigated:

(1) To determine a range in the bladder filling status which will serve as a potential notification threshold
(2) To determine a (theoretical) notification rate and full-bladder detection rate
(3) To determine how accurate the bladder volume can be estimated
(4) To evaluate the potential to determine residual urinal volume after voiding

Study design

This clinical investigation is designed according to the ISO 14155:2020 as follows:
• explorative

• prospective
• mono-center
• non-randomized
• single-arm with subjects
• uncontrolled
• open-label
• interventional
• feasibility study using the TENA-PROTO2

Intervention

The second prototype of the bladder sensor shall be evaluated with patients, who would not have tested this device otherwise.

Study burden and risks

There are no direct and primary anticipated clinical benefits of the TENA-PROTO2 for the participating subjects even if subjects, who are scheduled for urodynamics, would potentially benefit from the future TENA bladder sensor. However, TENA-PROTO2 will be used during urodynamics to collect data without any beneficial functionality for the subject at this development stage. However, results of this explorative feasibility study will be crucial for the sponsor to further develop the TENA Bladder Sensor, enabling users to be more in control of their bladder, by going to the bathroom in time and remain continent. The results will be used to, first, to determine minimum and maximum detectable bladder volume by TENA-PROTO2 and if there is a relation between the bladder filling status determined by the future algorithm and the infused bladder volume during urodynamics. Second, if there is a relation between the bladder filling status determined by the algorithm and the infused bladder volume, the following exploratory objectives will be investigated:

(1) To determine a range in the bladder filling status which will serve as a potential notification threshold
(2) To determine a (theoretical) notification rate and full-bladder detection rate
(3) To determine how accurate the bladder volume can be estimated
(4) To evaluate the potential to determine residual urinal volume after voiding

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Men and women defined by biological sex at birth
2. Individuals at the age of >= 18 years
3. Subjects who are scheduled for urodynamics
4. BMI >18.5 kg/m² and <= 39.9 kg/m²
5. Capability to understand the subject information and to provide conscious informed consent
6. Signed informed consent for study participation and data protection regulations
7. Willingness to conduct a urine pregnancy test for all female subjects < 55 years old. (Exceptions: the site team determines that the subject is not likely to become pregnant due to e.g., hysterectomy, postmenopausal.).
8. Capability and willingness to follow the study protocol and procedure of the urodynamics

Exclusion criteria

1. Subjects with breached skin, open wounds, sutures or major scar tissue in the suprapubic region

2. Subjects with suprapubic catheter
3. Subjects with implants that can be affected by electromagnetic interference (e.g. pacemaker)
4. Subjects who are pregnant or breast feeding
5. Known allergies or intolerances to one or several components of the study product
6. Alcohol abuse as reported by subject and/ or suspected by investigator that impacts capability to understand the subject information and to provide conscious informed consent in the discretion of the investigator
7. Drug abuse as reported by subject and/ or suspected by investigator that impacts capability to understand the subject information and to provide conscious informed consent in the discretion of the investigator
8. Objections of the investigator to the subject*s participation in the trial due to medical reasons or any other reason for which the subject should not participate in the opinion of the investigator
9. Participation in any clinical investigation with systemic and/or pharmaceutical substances within the last 4 weeks and/or in parallel
10. Sponsors, manufacturers or CRO staff

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	18-03-2024
Enrollment:	66
Type:	Actual

Medical products/devices used

Generic name:	TENA-PROTO2
Registration:	No

Ethics review

Approved WMO Date:	25-05-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	22-12-2023
Application type:	Amendment
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
ClinicalTrials.gov	NCT05305846
CCMO	NL80921.000.22