Safety and Performance of UCon for Management of Non-Neurogenic OAB in Males - An Early Feasibility Study

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Primary Safety Objective: • To evaluate initial safety of UCon for treatment of OAB symptoms in a home setting.Secondary Safety Objective• To demonstrate that subjects using UCon do not experience an unacceptable amount of device- or procedure...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON53594

Source
ToetsingOnline

Brief title
UCon Treatment of OAB in Males

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
Overactive bladder, Urgency-frequency

Research involving
Human

Sponsors and support

Primary sponsor: InnoCon Medical ApS
Source(s) of monetary or material Support: The sponsor;InnoCon Medical;is funding the clinical investigation.

Intervention

Keyword: Dorsal genital nerve (stimulation), Non-invasive neurostimulation, Overactive bladder, Urinary incontinence

Outcome measures

Primary outcome

Primary Safety Endpoint

• Characterization of adverse events and anticipated adverse device effects

associated with the use of UCon.

Primary Performance Endpoint

• Ratio of subjects with at least 50% improvement of their OAB symptoms from

baseline.

Secondary outcome

Secondary Safety Endpoint

• Frequency and severity of all adverse events and anticipated adverse device

effects associated with the use of UCon.

Secondary Performance Endpoint

• Ratio of subjects with improvement in their OAB specific quality of life

measures from baseline.

• Ratio of subjects that accept UCon and DGN stimulation.

Study description

Background summary

Overactive bladder is a serious and common healthcare problem, which can have

devastating impact on patient*s quality of life, as it includes embarrassment and severe social restrictions in many instances.
Treatment of overactive bladder consists mainly of medication, which are associated with significant side effects resulting in a large group of patients ending their treatment.
Within recent years neuromodulation has proven effective for treatment of OAB by stimulating nerve fibers in sacral roots (SNS) placed near the spinal cord. Despite the advantages and proven success of SNS, the initial costs of SNS are still considerable and the current device is an invasive device, implanted in the patient*s back.
The purpose of this study is to test a new medical device, UCon, which electrically stimulates a nerve at the genitals (Dorsal Genital Nerve, DGN) for the treatment of overactive bladder. UCon is designed with the stimulator being placed outside the body, thus designed at significant lower costs than implants. It also provides more possibilities to control and adjust treatment protocols for optimizing the effect for each individual patient. Thereby, UCon brings an affordable and minimally invasive treatment to the market helping a large group of patients suffering and currently left with poor treatment options, resulting in a poor quality of life.
The hypotheses are:
• UCon is safe for treatment of OAB in a home setting
• Subjects using UCon experience an improvement in their quality of life.
• Subjects using UCon do not experience an unacceptable number of device- or procedure related adverse events.
• Subjects accept UCon and DGN stimulation.

Study objective

Primary Safety Objective:
• To evaluate initial safety of UCon for treatment of OAB symptoms in a home setting.
Secondary Safety Objective
• To demonstrate that subjects using UCon do not experience an unacceptable amount of device- or procedure related adverse events.
Primary Performance Objective
• To evaluate the performance of UCon for treatment of OAB symptoms in a home setting.
Secondary Performance Objectives
• To evaluate whether subjects using UCon experience an improvement in their quality of life.
• To evaluate the device and treatment acceptability of UCon.

Study design

This clinical investigation is a randomized, cross-over, single-site, prospective, early feasibility study, which is used to evaluate the device with

respect to initial clinical safety and device performance in a small number of subjects.

Intervention

The intervention of this clinical investigation is neuromodulation obtained by electrical stimulation via UCon.
The subjects apply electrical stimulation 2 x 14 days. The cross-over design of the study enables the subjects to try two types of electrical stimulation.
I.e., the subjects receive one type of stimulation for the first period of the study, and then another type of stimulation during the second period of the study.
The stimulation types are:
Time-limited stimulation: 30 minutes stimulation each day, when it is convenient for the subject.
Urge stimulation: The subject activates stimulation when he experiences urgency during wake hours. The stimulation lasts for 60 seconds and can be stopped at any time.

Study burden and risks

During participation the subjects must:
- Visit the hospital 5-6 times
- Apply electrical stimulation for a minimum of 28 days
- Complete 3-days bladder diary 4 times
- Complete stimulation dairy 5 times
- Complete complications dairy 2 times
- Complete device and treatment satisfaction survey 2 times
- Complete Quality of Life Questionnaires 3 times

The risk associated with UCon treatment is very low. The primary method, electrical stimulation, is well-known and has been applied in similar studies, resulting in no long-lasting adverse events. If unanticipated adverse events should occur, treatment can simply be discontinued. As with equivalent medical devices, there is a risk of lack of effectiveness. However, much support for the effectiveness of DGN stimulation to treat OAB is provided in the literature. All risks identified in the risk analysis have been reduced as far as possible through risk control measures.
The subjects might experience improvement of their OAB symptoms during the stimulation periods and in a short period after. Due to this, the subjects will not have a lasting therapeutic benefit after completion of the investigation.
It is, however, expected that the results from the investigation will contribute to better treatment options for people suffering from OAB, which can lead to:
• Improvement of OAB symptoms
• Improved ability to perform daily activities such as grocery shopping, going to work, etc.

• Improved quality of life
Due to the few risks of UCon, serious harm to the subjects is very unlikely to occur. However, if stimulation with UCon in a home-healthcare setting is a viable solution for patients to treat their OAB symptoms, UCon will improve the treatment options and thereby the quality of life for these patients. Based on this, the disadvantages of conducting this investigation are minimal compared to the benefits that can be obtained.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Subject is >= 18 years of age.
- Subject is male.
- Subject is diagnosed with OAB

- Subject is able to communicate, provide feedback, understand and follow instructions during the course of the investigation.

Exclusion criteria

1. Subject is medically unstable (acute illness or complications of a chronic condition that might affect the subject*s participation in the investigation).
2. Subject has a Post Void Residual (PVR) of more than 100 ml or a Bladder Voiding Efficiency (BVE) of less than 75% (measured by uroflowmetry as the ratio of voided volume (VV) and total bladder capacity (VV+PVR)).
3. Subject has an active infection in the genital area incl. skin infections and UTI.
4. Subject has had botulinum toxin (BOTOX) treatment in the pelvic region within 6 months.
5. Subject has used antimuscarinics or β3 agonists within 14 days weeks*.
6. Subject has an implanted pacemaker, implantable drug pump or other active medical device (any medical device that uses electrical energy or other source of power to make it function).
7. Subject is enrolled or planning to enrol in another clinical investigation or was enrolled in an investigational drug study or medical device investigation within four weeks to enrolment.
8. Subject has neuropathy to a degree that is presumed to diminish the effect of the electrical stimulation.
9. Subject has a history of cancer in the pelvic region, are currently receiving cancer treatment, or has radiation-induced damage to the pelvic region.
10. Subject has addictive behaviour defined as abuse of alcohol, cannabis, opioids, or other intoxicating drugs.
11. Subject does not speak and understand Dutch.
*If a subject is currently being treated with antimuscarinics or β3 agonists, he is allowed to be included in the investigation, however, a washout period of 14 days is required before baseline can be established.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-11-2023
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	UCon
Registration:	No

Ethics review

Approved WMO Date:	15-02-2023
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL81593.000.22