A prospective study to assess the efficacy and safety of the BlueWind RENOVA iStim* System for the treatment of patients diagnosed with overactive bladder (OASIS - OverActive bladder StImulation System study)

Published: 23-05-2019
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To demonstrate efficacy and safety of the treatment of UUI with BlueWind RENOVA iStim* System therapy.

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

Summary

ID

NL-OMON55598

Source
ToetsingOnline

Brief title
BlueWind RENOVA iStim* System for the treatment of OAB

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
frequent need to urinate, Overactive bladder

Research involving
Human

Sponsors and support

Primary sponsor: BlueWind Medical Ltd.
Source(s) of monetary or material Support: industry

Intervention

Keyword: neurostimulation, overactive bladder, Urinary incontinence, Urology

Outcome measures

Primary outcome

Efficacy

• Proportion of responders at 6 months post system activation as demonstrated by >=50% improvement in average number of urgency related incontinence episodes, as measured by 7-day Patient Voiding Diary.

Overall study success criteria is defined as a lower 97.5% confidence bound for a single binomial proportion of >50% patient success at 6 months.

Safety

• Incidence of adverse events from implantation to 12-months post-activation

Secondary outcome

• Proportion of subjects with >=10 points (MID) improvement in HRQL (based on OAB-q) at 6 months post system activation

• Proportion of responders at 12 months post system activation as demonstrated by >=50% improvement in either average number of urgency related incontinence episodes or average number of severe/large urgency related incontinence episodes, as measured by 7-day Patient Voiding Diary.

• Proportion of responders at 6 months post system activation as demonstrated

by >=50% improvement in the average number of moderate-severe urgency epsiodes

PPIUS degree 3,4 or <8 voids/day

Study description

Background summary

Non-neurogenic lower urinary tract dysfunction or Overactive bladder (OAB) is a common urological chronic condition that significantly impairs the quality of life of those affected, with considerable financial costs. OAB ranks among the most prevalent and challenging problems in urology. Patients suffering from that condition may complain of urgency and frequency, urge incontinence, chronic pelvic pain or urinary retention. In most patients the etiology of these complaints remains unclear. Earlier reports estimated that about one in six adults in the United States and Europe have OAB .The prevalence of OAB increases with age thus it is expected that OAB will become more common in the future as the average age of people living in the developed world is increasing.
A European study reports that the prevalence of OAB in Europe has been estimated to be 15.6% and 17.4% for men and women respectively, with an overall prevalence of 16.6%. The American Urological Association reports studies showing rates as low as 7% to as high as 27% in men and rates as low as 9% to 43% in women. Urge incontinence was reported being higher in women. An estimated 455 million worldwide experienced at least one OAB symptom in 2008, with the prevalence expected to increase to 500 million in 2013 and 546 million in 2018.
In addition to clinical consequences and economic costs, OAB is associated with devastating losses in the quality of patient*s life. Patients with OAB often reduce their social activities, become isolated and are predisposed to depression. An array of pharmacologic, electromechanical, behavioral and surgical interventions is used to treat OAB. However, for a significant proportion of patients, response to treatment is poor and/or may be compromised by troublesome or severe side effects. Therefore, other treatment modalities, such as neuromodulation are needed to treat refractory OAB.
OAB is distinguished from other forms of urinary incontinence, including stress incontinence and dysfunctions associated with neurogenic disorders and surgical injury. The International Continence Society defines OAB as a condition characterized by symptoms of urinary urgency with or without urge incontinence, usually with urinary frequency (voiding eight or more times in a 24-hour period) and nocturia (awakening two or more times a night to void). The key symptom in OAB is urgency - defined as a sudden compelling desire to void,

which is difficult to defer. No precise cause for non-neurogenic OAB has been identified, with physiologic abnormalities ruled out by diagnostic evaluation. Although etiology remains elusive, a variety of risk factors are associated with the development of OAB including older age, side effects of medications, systemic chronic conditions, pregnancy/childbirth, neurological abnormalities, endocrine irregularities, functional and behavioral factors and lower urinary tract conditions.

Study objective

To demonstrate efficacy and safety of the treatment of UUI with BlueWind RENOVA iStim* System therapy.

Study design

Prospective, Interventional, Multi-center, single arm, open label study

Intervention

Treatment will include a daily stimulation of a minimum of 30 minutes per day and up to 120 minutes (a total of 2 hours per day), per physician discretion. Subject therapy parameters will be adjusted according to the individual patient sensations
Sensory and motor thresholds will be assessed and location of paresthesia sensation will be assessed and recorded. Tailored patient therapy parameters will be adjusted based upon patient tolerability, patient sensation and motor threshold. Stimulation parameters will be modified for each patient in a stepwise process, until a sensory response (tingling sensation in the ankle, foot, toes and sometimes a radiation sensation in the leg and/or genital area) OR a sensory response in combination with a motor response (flexion of the big toe, fanning out of digits 2-5, extension of the foot) is elicited. The optimal stimulation parameters selected will be comfortable and under the maximal tolerability intensity level.
Stimulation parameters range is given below:
• Frequency of up to 30Hz
• Peak current of up to 14mA
• Pulse width of up to 790µsec

Study burden and risks

The potential risks related to this study are the known risks of surgical and electrical stimulation. The sponsor and the investigators have determined that this study is justified because of the potential benefit to patient*s symptoms relief as a result of the BlueWind RENOVA system treatment effect.
Anticipated adverse events involved with the procedure are, but are not limited to, pain at stimulator site, ankle discomfort, implant migration or

displacement, infection, nerve injury, skin irritation, skin erosion, sensation of transient electric "shock"/ sudden radiating sensation / sporadic sensory response, technical device problems, seroma, formation of thrombosis and pulmonary embolism, allergic reaction, and potential temporary or permanent mobility impairment.

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

• 2 - Female aged 18 or greater (21 or greater in the US), with no plans to become pregnant
during the trial; if of bearing potential, negative pregnancy test and if sexually active, using
acceptable contraception.

• 4 - Diagnosis of UUI demonstrated on a 7-consecutive days voiding diary defined as
a minimum of nine (9) leaking episodes associated with urgency with at least one episode per
day for 5 days.
• 5 - More than or equal to 6 months history of UUI diagnosis
• 6 - Patient with inadequate response to any of the following conservative treatments (i.e.
dietary restriction, fluid restriction, bladder training, behavioral modification, pelvic muscle
training, biofeedback, etc.) and pharmacologic treatment.

Exclusion criteria

• 1 - Previous participation in another study with any investigational drug or device
within the past 90 days
• 5 - Any significant medical condition that is likely to interfere with study procedures,
device operation, or likely to confound evaluation of study endpoints
• 19 - More than minimal level of stress incontinence or mixed incontinence with stress
component likely to confound study outcome, based on a 7-day voiding diary or medical history,or when stress incontinence score in the MESA incontinence questionnaire is higher than the urgency incontinence score
• 28 - Have a life expectancy of less than 1 year

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-08-2019

Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	23-05-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-07-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-07-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-10-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-11-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-03-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-05-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-11-2020
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-02-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-12-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NCT03596671
CCMO	NL66519.091.18