BlueWind Medical system safety and performance in treatment of patients diagnosed with overactive bladder (OAB)) * amendment to allow extended follow up of the patients

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To evaluate BlueWind Medical RENOVATM System safety and performance in OAB patients for extended FU period of 36 months.

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

Summary

ID

NL-OMON44356

Source
ToetsingOnline

Brief title
BlueWind system for the treatment of OAB

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
OAB /Overactive bladder

Research involving
Human

Sponsors and support

Primary sponsor: BlueWind Medical
Source(s) of monetary or material Support: the industry/company as described in question B6/B7

Intervention

Keyword: overactive bladder, peripheral nerve stimulation, urology

Outcome measures

Primary outcome

The primary study endpoint is composed of: the incidence of serious adverse

events (system and/or procedure related events)

Secondary outcome

The secondary end point is composed of:

a. 36 month clinical improvement compared to baseline will be measured by the

effect of BlueWind Medical's therapy on the treatment of the following symptoms:

* Number of voids/day

* Volume voided/void

* Number of leaks per day

* Degree of urgency prior to void

In the presence of urge incontinence, the following factors should be evaluated

compared to baseline;

* Leaking episodes/day

* Severity of leaking episodes

* Absorbent pads replaced due to leaking/day

b. Regular measurement of sensory and motor threshold response to acute

stimulation (e.g., during parameter settings and at each follow up visit);

* Sensation threshold assessment- based on patient report

* Motor threshold assessment- based on physician visual observation

c. Quality of Life Questionnaire * OAB-q

Study description

Background summary

Overactive bladder (OAB) is a chronic condition that significantly impairs the quality of life of those affected, with considerable financial costs.
OAB is 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). OAB ranks among the most prevalent and challenging problems in urology. 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.
Patients with OAB often reduce their social activities, become isolated and are predisposed to depression. An array of conservative treatment options for OAB consists of behavioral techniques with or without biofeedback, bladder re-education, pelvic muscle exercises or pharmacotherapy. In addition surgical interventions may also be considered as optional treatment for OAB. However, for a significant proportion of patients, response to treatment is poor and/or may be compromised by troublesome or severe side effects.

Neuromodulation offers an alternative treatment for patients who do not respond or cannot tolerate a conservative treatment, and are not ready for irreversible surgery. Normal urinary control is dependent upon coordination among the nervous systems, the nerve pathways, bladder and sphincter. Unwanted, uncoordinated or disrupted signals along these pathways can lead to OAB. Therapy using neuromodulation incorporates electrical stimulation to target specific neural tissue.
To modulate bladder dysfunction, the stimulation signals must be delivered to the neural tissue affecting bladder activity. Different neuromodulative therapies, such as stimulation of the pudendal nerve, sacral nerve, and tibial nerve stimulation have been developed.
Tibial neuromodulation has been shown to reduce OAB symptoms and be safe. One

of the drawbacks to the therapy has been frequent office visits for the first 3 months and intermittent thereafter. However, BlueWind Medical has developed an implantable tibial nerve stimulator (neurostimulator) that is used at home, thus eliminating the necessity for frequent visits to the clinic.
In this study, the safety and performance of BlueWind neurostimulator is assessed in patients with overactive bladder. The system includes an implant, that will be placed in your lower leg in a minimally invasive surgery; and external control unit that is worn on your leg above the implant, once using the system. This control unit will allow you to self operate the system at home, and will assist you to adjust the therapy or turn the therapy on or off. Your doctor also has a device to control the amount of therapy the neurostimulator provides. Individual stimulation parameters will be set up for you by your doctor according to your sensations for optimal therapy impact.
The BlueWind therapy uses mild electrical pulses to stimulate the tibial nerve located at the lower leg. Stimulation will not cure your bladder problems. It may however reduce your symptoms to a tolerable level and allow you to resume many of your daily activities.
The BlueWind system is experimental and has not been approved for use outside of this research study.

Study objective

To evaluate BlueWind Medical RENOVATM System safety and performance in OAB patients for extended FU period of 36 months.

Study design

This study is designed as a prospective, observational, self-controlled study. It consists of baseline assessments, implantation of the BlueWind Medical system, system activation, treatment and follow-up visits for a 6 month period post implant activation.
The study will consist of the following activities;
* 1st visit- patient*s recruitment.
* 2nd visit-
- De novo Patient Group: BlueWind System compatibility test and diary screening.
- Prior-PTNS Patient Group: a Washout period.
* 3rd visit- BlueWind Medical System implantation.
* 4th visit- BlueWind Medical System activation (parameter setting and threshold assessment)
* 5th -7th visits- BlueWind Medical System Treatment and Follow Up
- Treatment cycles (1st and 2nd stimulation regimen cycles)
- Follow Up visit, including parameter adjustment, sensory and motor threshold assessment, quality of life questionnaire and a voiding diary.
8th-12th visits - BlueWind Medical System follow up visits;
- Treatment: The number of stimulations per week will be per physician

discretion.
- Follow Up visits, including parameter adjustment, sensory and motor thresholds assessments, quality of life questionnaire, voiding diary and assessment of patient compliance with treatment regimen.
At the first visit after the 6 month FU - The patients will be asked to consent to the study extension; and after receiving orientation regarding what is expected, tape measurements of the leg will be done (i.e. leg circumference, width and depth at different locations). In addition, during one of the follow up visits, tests will be performed in order to assess implant location:
1. Ultrasound; and/or
2. ECU height on the leg * medial malleolus to ECU center, with ECU placed in maximal position quality.

Intervention

The following intervention was part of the initial study. No new patients will undergo the intervention.
Study Treatment * Study will include two treatment regimens that will be prescribed for each patient. Patient will be asked to sit for the entire duration of the treatment. Each treatment regimen period will last for 3 months as follows:
* 1st regimen cycle- Six stimulation treatments per week, one stimulation per day, for duration of 30 minutes each.
* 2nd regimen cycle- Three stimulation treatments per week, one stimulation per day, for duration of 30 minutes each.
Parameter setting - An initial set of parameters will include:
Stimulation Frequency- 20 Hz
Pulse Width- 200 µsec
Amplitude- minimal settable level
Individual patient therapy parameters* will be adjusted based upon patient tolerability, patient sensation and motor threshold.
*Stimulation parameters will be tailored 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 motor response (flexion of the big toe, fanning out of digits 2-5, extension of the foot) is elicited. The intensity level selected will be comfortable (no pain sensation) and under the maximal tolerable threshold intensity.

During the extended FU study (FU visits 8th-12th) - The number of stimulations per week will be per physician discretion.

Study burden and risks

Current extension does not have addtional risks for the participants.
Participants will however have to come for addional (maximum 5) visits to the

hospital.

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. Participation in the original OAB pilot study
2. Signed written informed consent form (ICF) for the study extended FU period amendment
The original study consisted of the following inclusion criteria:
1. Signed ICF
2. Male or female aged 18 * 80.
3. Patient who is mentally competent with the ability to understand and comply with the requirements of the study.
4. Patient agrees to attend all follow-up evaluations and is willing to completely and accurately fill out voiding diaries and questionnaires, and is willing to complete required

exams and tests.
5. Patients with overactive bladder symptoms:
* Urinary frequency greater than 8 times/24 hours
AND/OR
* Urinary urgency leaks of at least 2 leaks on 3 day voiding diary
6. Patient who has failed conservative treatments after at least 6 months of treatment (i.e. lifestyle modification-fluid consumption, behavioral modification, and pharmacological therapy)
7. Patient who passes the BlueWind compatibility test.
8. Patients with competent sphincter mechanism.
9. Patients with normally functioning upper urinary tract.
10. Patients with no clinical evidence of a neurological S2-S4 motor sensory deficit.
11. Leg circumference in the range of 20-30 cm at implantation site.

Exclusion criteria

1. Patients whose BlueWind medical RENOVATM implant had been removed
The original study consisted of the following exclusion criteria:
1. Previous participation in another study with any investigational drug or device within the past 90 days.
2. Any metal implant in the area of BlueWind Medical implantation site.
3. Patients who have not had stable OAB medications for at least 30 days.
4. Patients who have received botulinum toxin injections within the past 6 months.
5. Patients who are receiving concomitant nerve stimulation therapies for OAB treatment, except for PTNS maintenance therapy.
6. Current pregnancy or attempting to get pregnant (female patient).
7. Previous urinary incontinence surgery or implantation of artificial graft material within the last 6 months.
8. Any spinal or genitourinary surgery within the last 6 months.
9. Previous abdominoperineal resection of the rectum or radical hysterectomy (female)/ prostatectomy (male) within the last 6 months.
10. Anatomical defects that preclude use of the device.
11. Pelvic pain disorders
12. Obvious clinically demonstrated genuine stress incontinence.
13. Any neurological disease or disorder including neuropathy or injury resulting in neuropathy.
14. Current urinary tract infection, presence of urinary stone and/or urinary tract malignancy (i.e. tumor, vesicourethral reflux, etc.)
15. Pelvic radiotherapy and chemotherapy.
16. Severe uncontrolled diabetes.
17. Patients anticipating magnetic resonance imaging (MRI) exams.
18. Presence of cystocele, enterocele or rectocele of grade 3 or 4.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-02-2015
Enrollment:	21
Type:	Actual

Medical products/devices used

Generic name:	The BlueWind Medical System
Registration:	No

Ethics review

Approved WMO Date:	06-01-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-01-2017
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
CCMO	NL50776.091.14