Axonics SacRal NeuromodulaTIon System for UrinAry Urgency Incontinence TreatmeNt

Published: 04-08-2017
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Primary Objective: To evaluate the safety and effectiveness of the Axonics Sacral Neuromodulation System as an aid in the treatment of the symptoms of Urinary Urgency Incontinence (UUI) designed to gain pre-market approval in the United States....

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

Summary

ID

NL-OMON48710

Source
ToetsingOnline

Brief title
ARTISAN-SNM

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
Overactive Bladder, Urinary Urgency

Research involving
Human

Sponsors and support

Primary sponsor: AXONICS MODULATION TECHNOLOGIES. INC
Source(s) of monetary or material Support: AXONICS MODULATION TECHNOLOGIES. INC

Intervention

Keyword: Incontinence, Neuromodulation, Sacral, Urge

Outcome measures

Primary outcome

Primary Effectiveness Endpoint:

Proportion of all implanted subjects that are Treatment Responders (i.e. subjects with *50% reduction in the number of urgency leaks) is greater than 50% at 6-months post activation.

Primary Safety Endpoint:

Rate of adverse events (AEs) at 6 months post-activation

Secondary outcome

Secondary Endpoints:

The following secondary endpoints are planned in all implanted subjects at 6-month follow-up

* Improvement from baseline in ICIQ-OABqol total score (HRQL)

* Reduction from baseline in average daily number of urgency leaks

* Reduction from baseline in average daily number of large urgency leaks

* Reduction from baseline in average daily urgency

* Improvement from baseline in average daily number of voids

Additionally, the following endpoint is planned in Trial Responders cohort at

6-month follow-up:

* Responder rate

Study description

Background summary

SNM is a well-established therapy for subjects with Urinary and Fecal dysfunction. To date, over 200,000 subjects worldwide have received InterStim® SNM implants. Improvements have been made to the device by Axonics Modulation Technologies Inc. While none of these advancements are expected to modify therapy, it is hypothesized that they may reduce adverse events, lower the risk profile and improve the patient experience.

Study objective

Primary Objective:

To evaluate the safety and effectiveness of the Axonics Sacral Neuromodulation System as an aid in the treatment of the symptoms of Urinary Urgency Incontinence (UUI) designed to gain pre-market approval in the United States.

Secondary Objective:

To evaluate the technical performance and health economics of the Axonics SNM System and the quality of life of patients in the treatment of the symptoms of UUI

Study design

Single-arm, prospective, multi-center, unblinded pivotal study

Intervention

All patients will receive the Axonics SNM System and will have to complete extra questionnaires and will have extra follow-up visits to standard of care.

Study burden and risks

Study protocol foresees 10 Follow-up (FU) visits per patient. At baseline visit and at each FU-visit patients will be asked to complete certain questionnaires in order to evaluate their quality of life. FU-visits shouldn*t take longer than 1 hour each.

During seven days before baseline visit and before each FU * visits, a voiding diary should be completed by the patient which will take about 1 hour to be filled out.

Contacts

Public
AXONICS MODULATION TECHNOLOGIES. INC

7575 Irvine Center Drives Suite 200
IRVINE Ca 92618
US
Scientific
AXONICS MODULATION TECHNOLOGIES. INC

7575 Irvine Center Drives Suite 200
IRVINE Ca 92618
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Diagnosis of UUI demonstrated on a 72-hour voiding diary defined as:
* a minimum of four (4) leaking episodes associated with urgency,
* at least 50% of all leaking episodes associated with urgency, and
* at least one leaking episode each 24-hour period. ;Greater than or equal to 6 months* history of UUI diagnosis;For male subjects only:
* Peak flow rate > 15 cc/s as verified by uroflowmetry within 6 months prior to enrollment
* Residual bladder volume < 150 cc tested within 6 months prior to enrollment;Positive motor response on at least two (2) implanted electrodes during intraoperative test in the S3 (preferred) or S4 foramen;21 years of age and older;For patients* over 70 years of age, or any patient at the discretion of the Investigator, Edmonton Frail Scale score of 9 or less;Failed conservative therapy and second-line drug therapy and is not a candidate for additional conservative or second-line therapy ;No changes to current regimen of medications that affect bladder function for at least four (4) weeks prior to beginning the baseline voiding diary and baseline questionnaires;Willing and capable of providing informed consent;Capable of participating in all testing associated with this clinical investigation

Exclusion criteria

More than minimal level of stress incontinence or mixed incontinence with stress component likely to confound study outcome. ;Current urinary tract mechanical obstruction (e.g. benign prostatic enlargement or urethral stricture);Interstitial cystitis or bladder pain syndrome as defined by either AUA or EAU guidelines;Chronic pelvic pain;History of any pelvic cancer;Uncontrolled hypertension;Any significant medical condition that is likely to interfere with study procedures, device operation, or likely to confound evaluation of study endpoints (e.g. Crohn*s disease, moderate to severe fibromyalgia, chronic pain, etc.);Any psychiatric or personality disorder at the discretion of the study physician;PHQ-15 score of *15 ;Current symptomatic urinary tract infection (UTI) or more than three (3) UTIs in past year;Any neurological condition that could interfere with normal bladder function, including stroke, epilepsy, multiple sclerosis, Parkinson*s disease, clinically significant peripheral neuropathy, or spinal cord injury (e.g., paraplegia);Uncontrolled diabetes (A1C > 6.5, documented in the last three (3) months) ;Diabetes with peripheral nerve involvement;Treatment of urinary symptoms with botulinum toxin therapy within twelve (12) months prior to SNM implant date;Treatment of urinary symptoms with tibial nerve stimulation within three (3) months prior to SNM implant date;Previously implanted with a sacral neuromodulation device;Underwent an external trial and was deemed a non-responder ;Pelvic organ prolapse stage 3 or higher;History of pelvic floor surgery, including surgical treatment for stress

incontinence or prolapse, within 6 months prior to SNM implant date;Surgical treatment for stress incontinence (sling, Burch or urethral injection) or pelvic organ prolapse recommended or planned at enrollment ;History of allergic response to titanium, zirconia, polyurethane, epoxy, or silicone;Knowledge of planned MRIs on areas other than the head, diathermy, or high output ultrasonic exposure;Any other active implanted devices (e.g., drug delivery pumps, pacemaker, ICD) including neurostimulators whether turned on or off. Passive implants (e.g., prostheses) are allowed, but no implanted metal should be at the Neurostimulator implant site;A female who is breastfeeding;A female with a positive urine pregnancy test ;Currently participating in another clinical trial

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):	06-12-2017
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Axonics Sacral Neuromodulation System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	04-08-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	20-09-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-10-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-04-2019
Application type:	Amendment
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	NL61843.068.17