Treatment of REfractory Overactive BLadder with the AXonics Sacral Neuromodulation System: RELAX-OAB

Published: 09-05-2016
Last updated: 19-04-2024

The RELAX-OAB is a post-market clinical follow-up (PMCF) study designed to confirm the safety and technical performance of the Axonics Sacral Neuromodulation (SNM) System as an aid in the treatment of the symptoms of overactive bladder (OAB). The...

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

Summary

ID

NL-OMON47196

Source
ToetsingOnline

Brief title
RELAX-OAB study

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
OAB, overactive bladder

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: OAB, post-market study, sacral neuromodulation

Outcome measures

Primary outcome

Primary Effectiveness Endpoint: Mean change in ICIQ-OABqol HRQL Total Score at

3 months compared to baseline

Safety Measures:

-Serious adverse device effects (SADEs)

-Adverse device effects (ADEs)

-Adverse procedure effects (APEs)

-Serious adverse events (SAEs)

-Adverse events (AEs)

Secondary outcome

Performance Measures:

-Device performance metrics

-Average leaks per day (3-day voiding diary)

-Average voids per day (3-day voiding diary)

-Percent of subjects with successful treatment, defined as either 1) a 50%

improvement in the number of average leaks or the number of voids per day or 2)

a return to a normal number of voids per day (<8 voids)

-Quality of life questionnaires (SF-12, EQ-5D, ICIQ-UI Short Form, ICIQ-OABqol,

I-QOL)

-Patient satisfaction with treatment

-Medication usage

-Healthcare utilization

Study description

Background summary

Millions of people experience bladder issues at some time. Overactive bladder is characterised by uncontrolled contractions of your bladder.
There are different types of overactive bladder:
*Frequent urges to urinate (urgency-frequency)
*Inability to hold urine/leaking (urge incontinence)

There are several treatment options for overactive bladder. Sacral nerve stimulation may be recommended for those people who have failed or could not tolerate more conservative treatments. This reversible treatment uses a small implanted neurostimulator to send mild electrical pulses to the sacral nerve to reduce symptoms.

The Axonics SNM system is a device that should address the shirtcomings of other commercially available neuromodulation devices.

Study objective

The RELAX-OAB is a post-market clinical follow-up (PMCF) study designed to confirm the safety and technical performance of the Axonics Sacral Neuromodulation (SNM) System as an aid in the treatment of the symptoms of overactive bladder (OAB). The secondary objectives of the RELAX-OAB study are to confirm the effectiveness, health economics, and quality of life of the Axonics SNM System as an aid in the treatment of the symptoms of OAB.

Study design

Single-arm, prospective, multi-center, unblinded study with each subject serving as their own control

Intervention

Implant of the Axonics SNM system.

Study burden and risks

Reproductive Risks
Pregnant women will be excluded from participation in this study. This restriction applies to the entire study period. Women of childbearing potential should therefore take reliable measures to prevent getting pregnant during the study. The treating doctor will discuss the most reliable method of contraception for the patient before she agrees to take part in this study. Should the patient, after having taken all the necessary precautions, nevertheless become pregnant during the study period, she must contact the investigator/treating doctor immediately. It is not known what the effects of your participation in this study will be to the unborn child.

Risks Due to the Stimulator and/or Procedure
The risks with surgically placing the Stimulator are similar to risks generally associated with surgery. The following risks and discomforts are likely to happen to the patient at least once:
* Change in sensation or magnitude of stimulation which has been described as uncomfortable (transient jolting or shocking) by some patients
* Heating at Stimulator implant location
* Pain or irritation at implant site
* Unintended nerve activation
The following risks and discomforts are possible, but unlikely to occur:
* Adverse change in voiding function (bowel and/or bladder)
* Allergic or immune system response to the implanted materials
* Infection
* Bruising, bleeding, blood collecting under the skin, or other fluid collecting under the skin at the implant site
* Burn at Stimulator implant location
* Nerve injury (including numbness)
* Lead or Stimulator moving away from original placement
* Lead or Stimulator causing the skin to thin or causing the device to be exposed
* Device malfunction

The amount of radiation to which the patient will be exposed will normally not differ from that of other sacral neuromodulation procedures, and should therefore not place the patient at any increased risk.

Unknown Risks
There may be side effects that are not yet known. The patient should call the study doctor if he/ she thinks that he/ she is having any of the problems listed above or even he/ she is having problems that are not on this list.

Amendment:
The risk of the examination is only the minimal exposure to X-rays of the two

shots. The radiation exposure is equal to 0.04 mSv.

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

- Diagnosis of OAB as demonstrated on a 3-day voiding diary defined as * 8 voids/day, and/or a minimum of two involuntary leaking episodes in a 72-hour period
- Positive motor response on at least two implanted electrodes during intraoperative test
- 18 years of age or older
- Failed, or are not a candidate for more conservative treatment (e.g., pelvic floor training, biofeedback, behavioral modification, oral pharmacotherapy)
No changes to current regimen of medications that affect bladder function for at least 4 weeks prior to beginning and completing 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

- Primary stress incontinence or mixed incontinence where the stress component overrides the urgency component
- Current urinary tract mechanical obstruction such as benign prostatic enlargement or urethral stricture
- Interstitial cystitis or bladder pain syndrome as defined by either AUA or EAU guidelines
- History of any pelvic cancer
- 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, etc.)
- Any psychiatric or personality disorder at the discretion of the study physician
- PHQ-9 Patient Depression Score * 10
- Current symptomatic urinary tract infection (UTI) or more than 3 UTIs in past year
- Any neurological condition that may interfere with normal bladder function, including stroke, multiple sclerosis, Parkinson*s disease, clinically significant peripheral neuropathy, or spinal cord injury (e.g., paraplegia)
- Severe or uncontrolled diabetes (A1C > 8, documented in the last 3 months) or diabetes with peripheral nerve involvement
- Treatment of urinary symptoms with botulinum toxin therapy in the past 12 months
- Treatment of urinary symptoms with tibial nerve stimulation in the past 3 months
- Previously implanted with a sacral neuromodulation device or participated in a sacral neuromodulation trial
- Subject with a documented 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 including neurostimulators (e.g., cochlear implant, pacemaker) and/or drug delivery pumps, 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 or of child-bearing potential with a positive urine pregnancy test or not using adequate contraception
- Participation in a current clinical trial or within the preceding 30 days

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):	13-06-2016
Enrollment:	36
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	09-05-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-11-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-12-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-05-2018

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-09-2018
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
ClinicalTrials.gov	NCT02620410
CCMO	NL55541.068.15

Study results

Date completed:	10-01-2022
Actual enrolment:	12

Summary results
Trial is onging in other countries