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Study to collect long-term clinical data for the recharge free Axonics SNM System (INS Model 4101)

Submission date
23/05/2024

Recruitment status
No longer recruiting

Registration date
28/05/2024

Overall study status
Completed

Last Edited
01/10/2025

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of the study is to obtain long-term clinical data for the recharge-free Axonics F15 SNM System (also referred to as INS Model 4101).

Who can participate?
Adults aged 18 or older, previously diagnosed with urinary urge incontinence (UUI) with or without urinary frequency (UF) and/or chronic fecal incontinence (FI), who received the Axonics F15 SNM System device and who have baseline bladder or bowel diaries.

What does the study involve?
The study involves a retrospective chart review of all F15 implants that took place ≥1-year post-implant, at selected centers. In addition, patients who have baseline bladder or bowel diaries will be prospectively enrolled and will complete one follow-up visit. The follow-up visit entails completing a post-operative bladder or bowel diary and a patient satisfaction questionnaire.

What are the possible benefits and risks of participating?
Benefit: The study will help gather long-term data on the recharge-free Axonics F15 SNM System (also referred to as INS Model 4101).
Risks: Similar to any sacral neuromodulation device indicated for overactive bladder disease and fecal incontinence.

Where is the study run from?
Axonics, Inc. (USA)

When is the study starting and how long is it expected to run for?
December 2023 to June 2025

Who is funding the study?
Axonics, Inc. (USA)

Who is the main contact?
Dr Karen Noblett, karen.noblett@bsci.com

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
105-0118

Study information

Scientific Title
F15 follow-up study

Study objectives
To obtain long-term clinical data for the recharge free Axonics F15 SNM System (also referred to as INS Model 4101).

Ethics approval required
Ethics approval not required

Ethics approval(s)
The study is a data collection effort whereby data is being collected retrospectively from those patients who were implanted with the Axonics SNM F15 device who are ≥ 1-year post-implant and who have baseline bladder or bowel diaries. Please note the device has been approved by the Food and Drug Administration (FDA) in the United States and Canada in 2022 and recently approved by the Therapeutic Goods Administration (TGA) in Australia in 2024.

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Other, Quality of life

Health condition(s) or problem(s) studied
Urinary urge incontinence (UUI) with or without urinary frequency (UF) and/or chronic fecal incontinence (FI)

Interventions
Multicenter, prospective study comparing bladder or bowel diaries at baseline to a minimum of 1 year follow up and up to 2 years if the participant is eligible (i.e., participants implanted between MarchJuly 2022). Participants will be identified through a retrospective chart review of all patients at the selected sites who were implanted with the Axonics F15 SNM and who have baseline bladder or bowel diaries. Device parameters and safety data will be collected, and a patient satisfaction questionnaire will be administered at the followup visit.

Intervention Type
Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Axonics F15 SNM System (also referred to as INS Model 4101)

Primary outcome(s)
Comparison from baseline to follow-up for the following:
1. ≥50% reduction in UUI episodes per day on a 3-day bladder diary OR
2. ≥50% reduction in FI episodes on a minimum of 5-day bowel diary

Key secondary outcome(s))
Comparison from baseline to follow-up for the following:
1. Complete urinary or fecal continence measured using a bladder or bowel diary
2. Device parameters (programming settings, impedance values) measured using the Clinician Programmer (CP), a tablet computer used by the clinician (or sponsor representative) to wirelessly communicate with the neurostimulator to check the device status and/or program the device
3. Procedure and/or device-related adverse events as reported in source documents by the physician and/or research staff
4. Serious adverse events (SAEs) as reported in source documents by the physician and/or research staff
5. Patient satisfaction measured using a Patient Satisfaction Questionnaire

Completion date
25/06/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 27/06/2025:
1. Aged 18 years or older
2. Provides written informed consent
3. Primary indication of UUI (with or without UF) or chronic FI who failed or could not tolerate more conservative treatments and implanted with the Axonics F15 SNM System and who have reached 1-year or greater, post-implant
4. Completion of a baseline pre-PNE 3-day bladder diary for UUI or a minimum of 5-day pre-PNE bowel diary for FI

Previous inclusion criteria:
1. Aged 18 years or older
2. Provides written informed consent
3. Primary indication of UUI (with or without UF) or chronic FI who failed or could not tolerate more conservative treatments and implanted with the Axonics F15 SNM System and who have reached 1-year or greater, post-implant
4. Completion of a baseline pre-PNE 3-day bladder diary for UUI or a minimum of 7-day pre-PNE bowel diary for FI
5. English speaking

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
69

Key exclusion criteria
1. Any significant medical condition that is likely to interfere with trial procedures, device operation, or likely to confound evaluation of trial endpoints (i.e., exclusion of neurological conditions such as multiple sclerosis)
2. Any psychiatric or personality disorder that is likely to interfere with trial procedures at the discretion of the participating physician; this may include poor understanding or compliance with trial requirements
3. A female who is breastfeeding
4. A female with a positive urine pregnancy test
5. Intradetrusor chemodenervation with OnabotulinumtoxinA (Botox) injections within 6 months prior to study follow-up visit
6. Prior history of pelvic or rectal cancer
7. Prior history of pelvic radiation

Date of first enrolment
27/03/2024

Date of final enrolment
22/04/2025

Locations

Countries of recruitment
United States of America

Study participating centre
Florida Bladder Institute
1890 SW Health Parkway, Suite 205
Naples
United States of America
FL 34109

Study participating centre
University of Cincinnati
51 Goodman Drive, Suite 530
Cincinnati
United States of America
Ohio 45221

Study participating centre
Urologic Solutions LLC
9400 Gladiolus Drive, Suite 30
Fort Myers
United States of America
FL 33908

Study participating centre
Southern Urogynecology
115 Midlands Court
West Columbia
United States of America
SC 29169

Study participating centre
Nevada Surgical
5500 Reno Corporate Drive
Reno
United States of America
NV 89511

Study participating centre
Urology Associates
134 Hoyle Avenue
Fairhope
United States of America
AL 36532

Study participating centre
Female Pelvic Health Center
760 Newtown Yardley Road

Suite 115
Newtown
United States of America
PA 18940

Study participating centre
Urology San Antonio
7909 Fredericksburg Road
Suite 110
San Antonio
United States of America
TX 78229

Sponsor information

Organisation
Axonics, Inc.

Funder(s)

Funder type
Industry

Funder Name
Axonics, Inc.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository called Medrio. Contact: Heather Waldeck, PhD (heather.waldeck@bsci.com)

Data will be made available in the form of a published manuscript in a peer-reviewed journal. The estimated time frame is August 2025.

IPD sharing plan summary
Stored in non-publicly available repository, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other unpublished results		21/07/2025	01/10/2025	No	No
Protocol file		15/05/2024	01/10/2025	No	No