Evaluation of InterStim Micro System Performance and Safety (ELITE) to Confirm Long-Term Outcomes.

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The purpose of this investigation is to confirm long-term clinical performance and safety of the InterStim Micro System. The primary objectives of the study will evaluate data at 3 months post-implant; however, subjects will be followed for 2 years...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON54995

Source
ToetsingOnline

Brief title
ELITE study

Condition

- Gastrointestinal motility and defaecation conditions
- Bladder and bladder neck disorders (excl calculi)

Synonym
Fecal incontinence, non-obstructive urinary retention, Overactive bladder

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic Trading NL BV
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: Fecal incontinence, InterStim Micro System, Non-Obstructive urinary retention, Overactive bladder

Outcome measures

Primary outcome

Overactive Bladder Cohort primary objective;

The primary objective for the overactive bladder cohort of the study is to

demonstrate an improvement

in Overactive Bladder Quality of Life (OAB-q) Questionnaire Health Related

Quality of Life (HRQL) total

score at 3 months post-implant compared to baseline.

Fecal Incontinence Cohort primary objective;

The primary objective for the fecal incontinence cohort of the study is to

demonstrate an improvement

in Cleveland Clinic Incontinence Score (CCIS) at 3 months post-implant compared

to baseline.

Non-Obstructive Urinary Retention Cohort primary objective:

The primary objective for the non-obstructive urinary retention cohort of the

study is to demonstrate an

improvement in number of clean intermittent self-catheterizations (CISC) per

day at 3 months postimplant

compared to baseline.

All additional objectives per cohort can be found under section 5 of the CIP.

Secondary outcome

Overactive Bladder Cohort primary objective;

• To characterize change in symptoms at follow-up visits compared to baseline

• To characterize the change in Overactive Bladder Quality of Life (OAB-q) Questionnaire Health Related Quality of Life (HRQL) total score and its subscales at follow-up visits compared to baseline

• To characterize the change in OAB-q symptom bother score at follow-up visits compared to baseline

• To characterize Patient Global Impression of Improvement (PGI-I) and patient satisfaction at follow-up visits

Fecal Incontinence Cohort primary objective;

• To characterize change in symptoms at follow-up visits compared to baseline

• To characterize the change in Cleveland Clinic Incontinence Score (CCIS) at follow-up visits compared to baseline

• To characterize change in Fecal Incontinence Quality of Life Questionnaire (FIQoL) at follow-up visits compared to baseline

• To characterize Patient Global Impression of Improvement (PGI-I) and patient satisfaction at follow-up visits

Non-Obstructive Urinary Retention Cohort primary objective;

• To characterize the change in number of clean intermittent

self-catheterizations (CISC) and associated symptoms per day at follow-up

visits compared to baseline

• To characterize the change In the Female Lower Urinary Tract Symptom (FLUTS)

Questionnaire and Male Lower Urinary Tract (MLUTS) Questionnaire at follow-up

visits compared to baseline

• To characterize Patient Global Impression of Improvement (PGI-I) and patient

satisfaction at follow-up visits

Study description

Background summary

Sacral Neuromodulation (SNM) is a treatment for bladder and bowel control symptoms through the modulation of sacral nerves. SNM is delivered by sending electrical pulses to the sacral nerve to modulate the neural activity that influences the behavior of the pelvic floor, lower urinary tract, urinary and anal sphincters, and colon. SNM delivered by the Medtronic InterStim System is an advanced therapy option for the treatment of the indications specified in the clinical investigational plan.1-4 Safety and performance have been established with long-term follow-up reported in the literature.5-7 This prospective clinical study will fulfill post-market clinical follow-up obligations for the InterStim Micro System and is an active mechanism to assess performance and safety in patients SNM therapy in an organized, systematic manner based on the intended use

Study objective

The purpose of this investigation is to confirm long-term clinical performance and safety of the InterStim Micro System.
The primary objectives of the study will evaluate data at 3 months post-implant; however, subjects will be followed for 2 years for the additional

measures and safety assessments.

Study design

A minimum of 50 subjects who complete the Three-month Follow-up Visit is required for the overactive bladder and fecal incontinence cohorts. A minimum of 30 subjects who complete the Three-month Follow-up Visit is required for the non-obstructive urinary retention cohort. Each subject will only be qualified for one of the study cohorts.
The study is intended to be conducted at approximately 40 centers in Europe, Canada, Australia and the United States (and United States Territories). This is an on-label, post-market study of an approved system. All subjects implanted in the study will
qualify under the approved indications for sacral neuromodulation.

Intervention

Please reffer to CIP page 16 to 19.

Study burden and risks

Participation in this study will not expose the subject to greater risks than if he/she were receiving an InterStim Micro System implant and sacral neuromodulation therapy with the InterStim Micro System outside of the study. The risks associated with an InterStim Micro System implant and sacral neuromodulation therapy with the InterStim Micro System are minimized in this study by selecting only qualified Investigators experienced in sacral neuromodulation, selecting an appropriate patient population via inclusion/exclusion screening, and monitoring subject progress and events reported for this study. The review and minimization of the potential risks to the patient and the potential benefits to the patient support the conduct of this study.
See CIP section 10 for more information

Contacts

Public
Medtronic Trading NL BV

Endepolsdomein 5
Maastricht 6229 GW
NL
Scientific
Medtronic Trading NL BV

Endepolsdomein 5
Maastricht 6229 GW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Overactive Bladder (OAB) Cohort Eligibility Criteria:
1. Have a diagnosis of OAB as demonstrated on a 3-day voiding diary with greater than or equal to 8 urgency frequency episodes per day and/or by having a minimum of 3 episodes of urinary urge incontinence in 72 hours
2. Subjects 18 years of age or older
3. Candidate for sacral neuromodulation therapy in accordance with the InterStim Micro System labeling
4. Willing and able to accurately complete study diaries, questionnaires, attend visits, device recharging and comply with the study protocol
5. Willing and able to provide signed and dated informed consent

Fecal Incontinence (FI) -Cohort Eligibility Criteria:
1. Have a diagnosis of fecal incontinence as demonstrated by a 7-day bowel diary as greater than or equal to 2 incontinent episodes of more than staining (i.e., either slight, moderate or severe soiling)
2. Subjects 18 years of age or older
3. Candidate for sacral neuromodulation therapy in accordance with the InterStim Micro System labeling
4. Willing and able to accurately complete study diaries, questionnaires, attend visits, device recharging and comply with the study protocol
5. Willing and able to provide signed and dated informed consent

Non-Obstructive UrinaryRetention (NOUR) - Cohort Eligibility Criteria:
1. Have a diagnosis of non-obstructive urinary retention as

demonstrated by a 7-day urinary voiding diary with a minimum of 5 clean intermittent self-catheterizations
2. Chronic non-obstructive urinary retention with an elevated postvoid residual (PVR) that has persisted for at least six months and is documented on two or more separate occasions.
3. Subjects 18 years of age or older
4. Candidate for sacral neuromodulation therapy in accordance with the InterStim Micro System labeling
5. Willing and able to accurately complete study diaries, questionnaires, attend visits, device recharging and comply with the study protocol
6. Willing and able to provide signed and dated informed consent

Exclusion criteria

Overactive Bladder (OAB) Exclusion criteria:
1. Have neurological conditions such as multiple sclerosis, clinically significant peripheral neuropathy or spinal cord injury (e.g., paraplegia)
2. Have primary stress incontinence or mixed incontinence where the stress component overrides the urge component
3. Current urinary tract mechanical obstruction (e.g. benign prostatic enlargement or urethral stricture)
4. Have had treatment of urinary symptoms with botulinum toxin therapy in the past 12 months
5. Have knowledge of planned shortwave diathermy, microwave diathermy, or therapeutic diathermy
6. Women who are pregnant or planning to become pregnant
7. Characteristics indicating a poor understanding of the study or characteristics that indicate the subject may have poor compliance with the study protocol requirements.
8. Concurrent participation in another clinical study that may add additional safety risks and/or confound study results.*

Fecal Incontinence (FI) Exclusion criteria:
1. Have neurological conditions such as multiple sclerosis, clinically significant peripheral neuropathy or spinal cord injury (e.g., paraplegia)
2. Uncorrected high grade internal rectal prolapse
3. Have knowledge of planned shortwave diathermy, microwave diathermy, or therapeutic diathermy
4. Women who are pregnant or planning to become pregnant
5. Characteristics indicating a poor understanding of the study or characteristics that indicate the subject may have poor compliance with the study protocol requirements.
6. Concurrent participation in another clinical study that may add additional safety risks and/or confound study results.*

Non-Obstructive Urinary Retention exclusion criteria :
1. Have neurological conditions such as multiple sclerosis, clinically significant peripheral neuropathy or spinal cord injury (e.g., paraplegia)
2. Current urinary tract mechanical obstruction (e.g. benign prostatic enlargement or urethral stricture)
3. Have knowledge of planned shortwave diathermy, microwave diathermy, or therapeutic diathermy .
4. Women who are pregnant or planning to become pregnant
5. Characteristics indicating a poor understanding of the study or characteristics that indicate the subject may have poor compliance with the study protocol requirements.
6. Concurrent participation in another clinical study that may add additional safety risks and/or confound study results.*

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-06-2022
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	InterStim Micro Implantable Neurostimulator (INS)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	08-10-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-09-2021
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
CCMO	NL72035.091.20