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A clinical study to evaluate HF10 therapy using surgical leads

Submission date
21/10/2019

Recruitment status
No longer recruiting

Registration date
22/10/2019

Overall study status
Completed

Last Edited
22/10/2019

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Spinal cord stimulation (SCS) involves implanting a device that delivers small electrical fields to the spinal cord to provide pain relief in patients with chronic (long-term), intractable (hard to control) back and leg pain. Significant leg pain relief has been reported with traditional SCS which uses a low frequency (<1200 Hz), but there is limited long-term data supporting the use of low-frequency SCS in predominant back pain patients. Recent studies testing SCS using a frequency of 10 kHz (HF10 Therapy™) have shown that this treatment is effective and safe in patients with both back and leg pain. The results from these studies demonstrated that these patients had significant pain relief up to 24 months. The decreased pain in both back and leg were consistent throughout the studies with improvements in functional capacity with no perception of paresthesia (a burning or prickling sensation). The aim of this study is to test the performance of HF10 therapy with the surgical lead worldwide in patients with back and/or leg pain, as per centers' routine practice.

Who can participate?
Patients aged over 18 with chronic, intractable back and/or leg pain

What does the study involve?
Participants undergo Spinal Cord Stimulation (SCS) at 10 kHz (HF10 therapy) as per the center's usual practice. SCS involves the surgical placement of a surgical lead (which looks like a thin wire) into a small area near the spinal cord. Electrical stimulation is delivered through this wire by a small, battery-operated, rechargeable SCS implanted generator. Each patient is followed for 12 months after device activation. The participants attend regular clinic visits to complete questionnaires and to provide feedback on their pain. Successfully treated participants get a permanent device implanted as per the center's routine clinical practice.

What are the possible benefits and risks of participating?
Participants may benefit from the SCS system to relieve their pain. There are no direct risks of taking part in this study, although the general risks of having a spinal stimulation device in place apply.

Where is the study run from?
Up to 40 pain centers in the USA and Europe

When is the study starting and how long is it expected to run for?
October 2018 to December 2021

Who is funding the study?
Nevro Corp (USA)

Who is the main contact?
Brad Gliner
gliner@nevro.com

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CA2018-4 INT SURPASS

Study information

Scientific Title
A prospective observational multicenter study of HF10 therapy using surgical leads

Acronym
SURPASS

Study objectives
The purpose of this study is to assess the clinical performance of HF10 therapy delivered to the spinal cord through SURPASS™ surgical leads in subjects with chronic, intractable, back and/or leg pain of neuropathic origin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
USA: Approved 29/11/2018, Western Institutional Review Board, 1019 39th Avenue SE Suite 120, Puyallup, WA 98374-2115, USA; Tel: +1 (360) 252-2500, +1 (800) 562-4789; Email: clientservices@wirb.com), IRB Tracking Number: 20183112
Belgium: Approved 14/05/2019, AZ Delta, Commissie voor Medische Ethiek (Rode Kruisstraat 20, 8800 Roeselare, Belgium; Tel: +32 (0)56 52 22 31; Email: sigrid.deneve@azdelta.be), ref. 19019

Study design
Multi-center prospective observational clinical study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic, intractable, back and/or leg pain of neuropathic origin

Interventions
As part of their standard care, participants undergo a trial (temporary evaluation period) of Spinal Cord Stimulation (SCS) at 10 kHz (HF10 Therapy) as per the center’s usual practice and following this, those for whom the trial treatment was successful have a permanent device implanted as per center’s routine clinical practice.

Following device activation, participants are followed for a period of 12 months. The participants attend regular clinic visits, at 3, 6 and 12 months, to complete questionnaires, and to provide feedback on their pain, quality of life, disability, health status, satisfaction and work status. At these visits, the physicians will take assessments from the participants such as pain evaluation, medication usage and side effects (if any).

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Responder rate at 3 months (a responder is defined as a subject who experiences ≥30% pain reduction compared to baseline as assessed by NRS & improvement in health status per the patient global impression of change questionnaire)

Key secondary outcome(s))
1. Pain is measured using the numerical rating scale (NRS) at baseline, end of trial, 3, 6 and 12 months
2. Disability is measured using the Oswestry Disability Index (ODI) at baseline, 3, 6 and 12 months
3. Quality of life is measured using the EQ-5D-5L at baseline, 3, 6 and 12 months
4. Opioid intake is measured using a medication log at baseline, end of trial, 3, 6, 12 months
5. Health status is measured using the patient/physician global impression of change questionnaire at end of trial, 3, 6, 12 months
6. Participant satisfaction with the therapy is measured using the subject satisfaction questionnaire at 3,6 and 12 months

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Have chronic intractable back pain and/or leg pain of neuropathic origin, as determined by the physician
2. An appropriate candidate for spinal cord stimulation and/or surgical lead placement as determined by the physician
3. Already scheduled for either a commercial trial with Nevro or a permanent implant of the Senza system (with surgical lead only)
4. Be 18 years of age or older at the time of enrollment
5. Be able to read and understand the Patient Informed Consent Form
6. Be willing and capable of giving informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Contraindicated for surgical lead placement and/or spinal cord stimulation; physician should reference labeling for precautions, warnings and indications

Date of first enrolment
06/05/2019

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Belgium

United States of America

Study participating centre
AZ Delta
Roeselare
Belgium
8800

Study participating centre
Albany Medical College
Albany
United States of America
NY 12208

Study participating centre
Neuroscience Group
1305 W American Dr
Neenah
Wisconsin
United States of America
54956

Sponsor information

Organisation
Nevro Corp

ROR
https://ror.org/02xcxe208

Funder(s)

Funder type
Industry

Funder Name
Nevro Corp

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Brad Gliner (gliner@nevro.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes