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A clinical study to evaluate pain perception with spinal cord stimulation

Submission date
26/07/2016

Recruitment status
No longer recruiting

Registration date
27/07/2016

Overall study status
Completed

Last Edited
17/12/2019

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Back pain is a common condition which affects most people at some point in their lives. In some people, back pain can be so severe that the only effective treatment is surgery. If this is the case, the surgery usually aims to either reduce pressure on a nerve that is compressed or to stabilise a painful joint or disc in the back, depending on the underlying cause of the back pain. Failed back surgery syndrome (FBSS) is a general term used to describe patients who have not had a successful result after surgery on their back or spine and continue to experience pain after the procedure. The Nevro Senza SCS system is device which is implanted in the back to help relieve severe back pain by stimulating the spinal cord. Unlike traditional spinal stimulation devices, the Senza system delivers high frequency stimulation at low amplitudes, and so provides pain relief without a tingling sensation. The aim of this study is to learn more about how to further improve the Senza treatment by investigating aspects such as the stimulation settings and its effect on pain perception.

Who can participate?
Patients aged over 18 with predominant back pain after a failed back surgery

What does the study involve?
Participants undergo a trial of Spinal Cord Stimulation at 10 kHz (HF10 Therapy) as per the center's usual practice. Successfully trialed participants get a permanent device implanted as per center's routine clinical practice. During the study the stimulation settings are adjusted and changes in pain perception, if any, are documented. During this period, the effect of SCS on back pain is evaluated. The participants attend regular clinic visits to complete questionnaires, and to provide feedback on their pain perception.

What are the possible benefits and risks of participating?
Participants may benefit from the SCS system to relieve their back 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?
1. AZ Nikolaas Multidisciplinary Center (Belgium)
2. AZ Delta Multidisciplinary Center (Belgium)

When is the study starting and how long is it expected to run for?
March 2016 to December 2018

Who is funding the study?
Nevro Corp (USA)

Who is the main contact?
Wim Laloo

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CA2016OUS PPE

Study information

Scientific Title
Pain perception evaluation with paresthesia independent spinal cord stimulation therapy

Study objectives
The aim of this study is to assess the pain perception in HF10™ electrical stimulation delivered to the spinal cord in subjects with chronic, intractable back pain as per the center's routine practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
AZ Delta Commissie Medische Ethiek, 12/07/2016, ref. B117201628681

Study design
Multicenter prospective interventional randomized clinical study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Failed back surgery syndrome

Interventions
Eligible subjects with predominant back pain after a failed back surgery will undergo a trial of Spinal Cord Stimulation (SCS) at 10 kHz (HF10 Therapy) as per the center’s usual practice. Successfully trialed subjects will get a permanent device implanted as per center’s routine clinical practice. During the study the stimulation settings will be adjusted and changes in pain perception, if any, will be documented. During this period, the effect of SCS on back pain will be evaluated. The participants will attend regular clinic visits to complete questionnaires, and to provide feedback on their pain perception.

Intervention Type
Device

Primary outcome(s)
1. Back pain intensity assessed by numeric rating scale (NRS) at baseline, at the end of the trial and at post-IPG monthly follow-up visits (1, 2, 3, 4, 5 and 6 months)
2. Leg pain intensity assessed by NRS at baseline, at the end of the trial and at post-IPG monthly follow-up visits (1, 2, 3, 4, 5 and 6 months)
3. Pain quality assessed by SF-MPQ at baseline, at the end of the trial and at post-IPG 3 and 6 month follow-up visits
4. Neurological assessment at baseline and at post-IPG 3 month follow-up visit
5. Level of catastrophic thinking assessed by the Pain Catastrophizing Scale – PCS at baseline, at the end of the trial and at post-IPG 3 and 6 month follow-up visits
6. Emotional mood assessed by the State Trait Anxiety Inventory – STAI Y1-Y2 at baseline, at the end of the trial, and at post-IPG follow-up visits
7. Assessment of the subject’s condition and device use during follow-up, performed during the Weekly Telephone Interview (NRS pain, physical activity, medication use, adverse events, device usage)
8. Depression assessed by the Beck Depression Inventory – BDI-II at baseline, at the end of the

trial, and at post-IPG 3 and 6 month follow-up visits
9. Assessment of the subject’s expectation with therapy assessed by NRS rating at enrolment
10. Assessment of the subject’s fulfillment of his expectation at the end of the trial and post-IPG monthly follow-up visits (1, 2, 3, 4, 5 and 6 months), assessed by NRS rating
11. General state of health assessed by the Patient Global Impression of Change instrument - PGIC at baseline, at the end of the trial and at post-IPG 3, 4 and 6 month follow-up visits
12. General state of health assessed by the Clinician Global Impression of Change instrument - CGIC at baseline, at the end of the trial and at post-IPG 3, 4 and 6 month follow-up visits
13. Assessment of medication usage at every visit
14. Assessment of rescue medication usage during post-IPG monthly follow-up visits (1, 2, 3, 4, 5 and 6 months)
15. Assessment of subject's satisfaction with therapy and device at the 3 and 6 month follow-up visits
16. Incidence of unanticipated adverse device effects (UADEs) at every visit

Key secondary outcome(s))
No secondary outcome measures

Completion date
31/03/2019

Eligibility

Key inclusion criteria
1. Diagnosed with failed back surgery syndrome with predominant back pain
2. Average back pain intensity of ≥ 5 out of 10 on the Numeric Rating Scale (NRS) at enrollment
3. An appropriate candidate for Spinal Cord Stimulation as per the Belgian regulations
4. An adult (≥ 18 years of age) at time of enrollment
5. Evaluated at the investigational site at least once prior to screen for the pain condition related to the study
6. Willing and capable of giving written informed consent prior to any investigational related procedure
7. Willing and able to comply with study-related requirements, assessments and visits
8. Capable of subjective evaluation, able to read and understand written questionnaires, and able to read, understand and sign the written inform consent (Dutch and French)
9. Adequate cognitive ability to use a patient external trial stimulator and recharger as determined by the Investigator
10. An appropriate candidate for the surgical procedures required in this study based on the clinical judgment of the implanting physician and if applicable per the local regulations
11. On stable pain medications, as determined by the Investigator, for at least 4 weeks prior to the baseline visit
12. A stable physical activity level, as determined by the Investigator and activity diary, for at least 2 weeks prior to the baseline visit

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Using an daily opioid dose of >60mg oral morphine equivalents (meq) or daily >25 µg/hr transdermal fentanyl
2. A medical condition or pain in other area(s), not intended to be treated with SCS, that could interfere with study procedures, accurate pain reporting, and/or confound evaluation of study endpoints
3. Evidence of an active disruptive psychological or psychiatric disorder or other known condition significant enough to impact perception of pain, compliance of intervention and/or ability to evaluate treatment outcome, as determined by a psychologist
4. A current diagnosis of a progressive neurological disease such as multiple sclerosis, chronic inflammatory demyelinating polyneuropathy, rapidly progressive arachnoiditis, rapidly progressive diabetic peripheral neuropathy, brain or spinal cord tumor, or severe/critical spinal stenosis
5. A visceral pain in the area being treated
6. A current diagnosis of a coagulation disorder, Complex Regional Pain Syndrome (CRPS), bleeding diathesis, progressive peripheral vascular disease or uncontrolled diabetes mellitus
7. A diagnosis of scoliosis that precludes lead placement
8. Recent evidence (imaging or letter neurosurgeon) of spinal instability requiring fusion (imaging such as flexion/extension films of lumbar spine is required for this determination and must have been done within the past 6 months)
9. Pain that is significantly exacerbated by activity or significantly alleviated by rest
10. Benefiting within 30 days prior to enrollment from an interventional procedure and/or surgery to treat back and/or leg pain
11. An existing drug pump and/or SCS system or another active implantable device (switched on or off) such as a pacemaker or other SCS devices
12. Prior experience with SCS
13. A condition currently requiring or likely to require the use of MRI in the trunk
14. Metastatic malignant disease or active local malignant disease
15. A life expectancy of less than 1 year
16. An active systemic or local infection
17. Pregnant (if female and sexually active, subject must be using a reliable form of birth control, be surgically sterile or be at least 2 years post-menopausal)
18. Within 6 months of enrollment a significant untreated addiction to dependency producing medications or have been a substance abuser (including alcohol and illicit drugs)
19. Limited physical activity not due to back pain (due to e.g. knee arthrosis, arthroplasty)
20. Concomitantly participating in another clinical study, or planned to be enrolled in another clinical study and/or data collection
21. Involved in an injury claim under current litigation
22. A pending or approved worker’s compensation claim

Date of first enrolment
01/10/2016

Date of final enrolment
01/05/2017

Locations

Countries of recruitment
Belgium

Study participating centre
AZ Nikolaas Multidisciplinary Center
Belgium
9100

Study participating centre
AZ Delta Multidisciplinary Center
Belgium
8800

Sponsor information

Organisation
Nevro Corp (USA)

ROR
https://ror.org/02xcxe208

Funder(s)

Funder type
Industry

Funder Name
Nevro Corp (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

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