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A clinical study to investigate the preference of medial and lateral stimulation with the Nevro Senza Spinal Cord Stimulation system

Submission date
02/02/2017

Recruitment status
No longer recruiting

Registration date
03/02/2017

Overall study status
Completed

Last Edited
17/12/2019

Condition category
Signs and Symptoms

[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
Worldwide, one in five people suffer from moderate to severe long-term (chronic) pain. Of these, one in three is unable or less able to maintain an independent lifestyle due to pain. Between 50-60% of people with chronic pain are less able or even unable to exercise, sleep normally, perform household chores, attend social activities, drive a car, or walk. Spinal cord stimulation (SCS) is a treatment for low back pain which involves delivering electrical impulses to the spinal cord via multi-contact leads implanted in the back. The exact mechanism behind the pain-relieving effects of SCS is not fully understood, but many believe that SCS modulates nerves of the upper part of the spinal cord to reduce the pain sensation. SCS is considered to be a minimally invasive, reversible therapy that may provide greater long-term benefits over more invasive surgical approaches. Decades of clinical experience demonstrate SCS can be an effective therapy for certain types of pain. The Nevro Senza SCS system is a device which is implanted in the back to help relief 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 further investigate the Senza system to investigate the degree to which laterally-positioned (to the side) leads can achieve low back pain relief.

Who can participate?
Adults with long-term low back pain and who are considered for spinal cord stimulation.

What does the study involve?
All participants receive spinal cord stimulation (SCS). This involves having two leads (very thin wires) placed into a small area near the spinal cord surgically. Electrical stimulation is then delivered via these wires in an attempt to provide pain relief, by a small, battery-operated, rechargeable SCS implanted generator. Stimulation is provided as per standard practice. During the study, the leads are stimulated in a difference order and participants do not know which of the leads is activated first. During this phase of the study, participants are asked to complete questionnaires related to their pain condition and at the end of the study their preference of stimulation phase.

What are the possible benefits and risks of participating?
Participants may benefit from finding a better lead placement during their trial stimulation providing better pain relief for them. Knowledge gained from this study will enable better informed guidance for 'best practice' lead placement for Senza leads, as well as possible insights into mechanisms of HF10 therapy. 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?
Monash Clinical Research (Australia)

When is the study starting and how long is it expected to run for?
February 2017 to June 2019

Who is funding the study?
Nevro Corp (USA)

Who is the main contact?
1. Mr Wim Laloo (public)
2. Mr Kerry Bradley (scientific)

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CA2016OUS ML

Study information

Scientific Title
Prospective Controlled Clinical Trial of Medial & Lateral Stimulation Using the Senza™ Spinal Cord Stimulation (SCS) System

Acronym
SENZA-Medial & Lateral

Study objectives
The aim of this study is to assess the relative efficacy of HF10™ therapy delivered from a lateral position in the spinal column compared to the standard medial position in subjects with chronic, intractable predominant low back pain as per the centre's routine practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bellberry Ethics Committee, 02/02/2017, ref: 2016-12-890

Study design
Single-center prospective single-blind non-randomised feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Chronic, intractable predominant low back pain

Interventions
Following enrollment eligible subjects will be entering a SCS trial phase. SCS involves the surgical placement of two leads (which look like very thin wires) into a small area near the spinal cord. Electrical stimulation is delivered through these wires, in an attempt to provide pain relief, by a small, battery¬-operated, rechargeable SCS implanted generator. For the SCS trial phase an external trial stimulator will be used. The intervention, medial and lateral stimulation activation, will happen during the trial phase. The trial phase is performed per routine practice before a SCS system is implanted permanently. The subjects will be blinded to the order of medial and lateral leads activation during the trial phase. This means that the subjects will not know which leads will be activated first. During this phase the subjects will be asked to complete questionnaires related to their pain condition and at the end of the study their preference of stimulation phase.

Intervention Type
Device

Primary outcome measure
Pain relief is assessed using a numerical rating scale (NRS) at 7 days +/- 5 days and 14 days +/- 5 days

Secondary outcome measures
1. Low back pain intensity is measured using Numerical Rating Scale (NRS) values recorded in pain diaries at 7 days +/- 5 days and 14 days +/- 5 days
2. Leg pain intensity is measured using Numerical Rating Scale (NRS) values recorded in pain diaries at 7 days +/- 5 days and 14 days +/- 5 days
3. Clinician global impression of change (CGIC) is assessed by the Clinician Global Impression of Change scale at 7 days +/- 5 days and 14 days +/- 5 days
4. Subject global impression of change (PGIC) is assessed by the Patient Global Impression of Change scale at 7 days +/- 5 days and 14 days +/- 5 days
5. Subject preference for medial or lateral stimulation is assessed by the Subject Preference Questionnaire at 14 days +/- 5 days
6. Incidence of unanticipated adverse device effects (UADEs) is observed at 7 days +/- 5 days and 14 days +/- 5 days

Overall study start date
19/04/2016

Completion date
09/06/2019

Eligibility

Key inclusion criteria
1. Diagnosed with chronic, intractable predominant pain of the low back with or without leg pain
2. Considering daily activity and rest, report a recall average NRS score for low back pain of ≥5, and leg pain less than low back pain, during the previous 14 days prior to study enrollment
3. An appropriate candidate for HF10™ therapy and for the surgical procedures required in this study based on the clinical judgment of the implanting physician
4. Previously agreed to receive a Senza SCS system and participate in a trial phase
5. If taking them, be on stable chronic pain medications, as determined by the Investigator, for at least 28 days prior to enrolling in the study and be willing to stay on those medications with no

dose adjustments until study completion or study withdrawal, whichever comes first
6. 18 years of age or older at the time of enrollment
7. Willing and able to comply with study-related requirements, procedures, and visits
8. Capable of subjective evaluation, able to read and understand ethics committee (EC) approved written questionnaires, and are able to read, understand and sign the EC-approved written informed consent, all of which will be in Australian English
9. Capable of subjective evaluation, able to read and understand questionnaires, and are able to read, understand and sign the written inform consent, all of which will be in Australian English
10. Adequate cognitive ability to use a patient programmer and recharger as determined by the Investigator

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Mmedical 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, as determined by the Investigator
2. 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 the investigator and the subject’s medical history
3. 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, central deafferentation syndrome, Complex Regional Pain Syndrome, or acute herniating disc, as determined by the investigator
4. Any clinical evidence mechanical instability or progressive neurologic pathology that warrants surgical intervention
5. Undergone an interventional procedure and/or surgery to treat low back or leg pain in the last 30 days
6. A condition currently requiring or likely to require diathermy
7. A condition currently requiring or likely to require surgery during the study period
8. Metastatic malignant disease or active local malignant disease
9. Life expectancy of less than 1 year
10. Active systemic or local infection
11. Pregnancy or plans to become pregnant during the course of the study (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)

12. A significant untreated addiction to dependency producing medications or have been a substance abuser (including alcohol and illicit drugs) within 6 months of enrollment
13. Concomitant participation or plans to participate in another clinical study overlapping in time with the present clinical study.
14. An existing drug pump and/or another active implantable device (switched On or Off) such as a pacemaker or other non-Senza SCS devices

Date of first enrolment
10/02/2017

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Australia

Study participating centre
Monash Clinical Research
Monash House
Clayton Road 271
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Australia
VIC3168

Sponsor information

Organisation
Nevro Corp

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1800 Bridge Parkway
Redwood City
United States of America
CA94065

Sponsor type
Industry

ROR
https://ror.org/02xcxe208

Funder(s)

Funder type
Industry

Funder Name
Nevro Corp

Results and Publications

Publication and dissemination plan
1. Planned presentation of results to international congresses
2. Planned publication in a peer reviewed journal

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Verrills (pverrills@metropain.com.au_

IPD sharing plan summary
Available on request