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A clinical study to investigate the preference of new programming settings with the Nevro Senza Spinal Cord Stimulation system

Submission date
01/03/2016

Recruitment status
No longer recruiting

Registration date
04/03/2016

Overall study status
Completed

Last Edited
25/03/2022

Condition category
Nervous System Diseases

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

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 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. Duty-cycled (DC) programs are where the stimulation provided by the device alternated between on and off at alternating patterns for a series of miliseconds. The aim of this study is to compare three of these DC programs to find out which is preferred by FBSS patients at providing pain relief.

Who can participate?
Adults with back pain because of FBSS, who have had a Nevro Senza SCS system fitted in their back for at least three months and use the system in a single area for at least 18 hours a day.

What does the study involve?
All participants try three different duty-cycled (DC) programs. The first program involves 100% duty cycled program for 7 days (continuous stimulation). The second program involves a 14% duty cycle period for 10-14 days. Patients who do not prefer 14% DC have their Senza system programmed with 50% DC for a further 10-14 days. The participants keep a pain diary throughout the duration of each program. Between program evaluation periods, participants return to the clinic to complete questionnaires, to have new programs enabled, and to provide feedback on their preference for the different programs.

What are the possible benefits and risks of participating?
Participants may benefit from finding a different program that is more effective at providing

pain relief for them. 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?
Metro Pain Group (Australia)

When is the study starting and how long is it expected to run for?
December 2015 to April 2017

Who is funding the study?
Nevro Corp (USA)

Who is the main contact?
Mr Wim Laloo

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CA2015OUS DC

Study information

Scientific Title
Prospective clinical trial of duty cycled stimulation using the Senza™ Spinal Cord Stimulation (SCS) System

Study objectives
The aim of this study is to assess the preference for duty-cycled (DC) HF10™ electrical stimulation delivered to the spinal cord in subjects with chronic, intractable back pain with or without leg pain as per the center's routine practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bellberry Ethics Committee, 12/02/2016, ref: 2015-12-87

Study design
Single-center prospective non randomised 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
Failed Back Surgery Syndrome (FBSS)

Interventions
The study participants will try 3 different duty-cycled (DC) programs (3%, 14%, 50% DC). They will use these programs identically to how they use their stimulation for everyday therapy, e.g. for more than 18 hours per day for approximately 10-14 days, for each program (i.e. they use the device in the same way as normal therapy). The participants will be first evaluated with their 100% duty cycled program for 7 days (100% duty cycling means continuous stimulation), then

they will proceed to a 14% duty cycle period for 10-14 days. If the participant prefers 14% DC they will be programmed with 3% DC for 10-14 days. In case they didn’t prefer 14% DC they will be programmed with 50% DC for 10-14 days.

Intervention Type
Other

Primary outcome measure
The proportion of subjects expressing preference for any <100%DC stimulator program [Treatment] or no preference, versus preference for the 100%DC stimulator program [Control] for all subjects successfully completing the end of other duty cycle assessments phase using Senza SCS HF10 therapy is measured using the Preference Questionnaire at 3 and 5 weeks.

Secondary outcome measures
1. Back pain intensity is determined using Numerical Rating Scale (NRS) values as assessed using the participant's pain diary at baseline, 3, 5 and 17 weeks
2. Leg pain intensity is determined using Numerical Rating Scale (NRS) values as assessed using the participant's pain diary at baseline, 3, 5 and 17 weeks
3. Patient's Global Impression of change at 17 weeks
4. Clinician's Global Impression of change at 17 weeks
5. Adverse events are measured through self-reporting at all study visits (scheduled and unscheduled)
6. Subject satisfaction measured by the Subject Satisfaction questionnaire (questionnaire is specifically designed for this study) at 17 weeks

Overall study start date
02/12/2015

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Have been diagnosed with chronic, intractable pain of the back pain with or without leg pain secondary to Failed Back Surgery Syndrome (FBSS)
2. Have been implanted with the Nevro Senza SCS system with dual leads, approximately over vertebral T8-T11, for at least 3 months, and are using the system with single area, continuous 10 kHz stimulation programs at least 18 hours daily, as determined by subject reporting and confirmation via device diagnostics, for at least 21 days prior to enrolling in this study
3. 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
4. Be 18 years of age or older at the time of enrollment
5. Be willing and able to comply with study-related requirements, procedures, and visits
6. Be 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
7. Be compliant in using the patient programmer and recharger as determined by the Investigator
8. As determined by the Investigator, be compliant in adjusting programs using the device

remote control
9. Considering daily activity and rest, report a recall average back pain relief of > 50% compared with pre-implant and a recall average NRS score for back pain of <5 during the previous 14 days prior to study enrollment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Total final enrolment
31

Key exclusion criteria
1. Have 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, as determined by the Investigator
2. Have 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
3. Have 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, central deafferentation syndrome, Complex Regional Pain Syndrome, or acute herniating disc, as determined by the investigator
4. Having any clinical evidence mechanical instability or progressive neurologic pathology that warrants surgical intervention
5. Having undergone an interventional procedure and/or surgery to treat back or leg pain other than Senza HF10 therapy in the last 30 days
6. Have a condition currently requiring or likely to require diathermy
7. Have a condition currently requiring or likely to require surgery during the study period.
8. Have metastatic malignant disease or active local malignant disease
9. Have a life expectancy of less than 1 year
10. Have an active systemic or local infection
11. Be pregnant or planning 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. Have within 6 months of enrollment a significant untreated addiction to dependency producing medications or have been a substance abuser (including alcohol and illicit drugs)
13. Be concomitantly participating or planned to be participating in another clinical study overlapping in time with the present clinical study

14. Have an existing drug pump and/or another active implantable device (switched On or Off) such as a pacemaker or other non-Senza SCS devices
15. Have an unresolved condition of device-related pain (e.g. IPG pocket pain)

Date of first enrolment
01/03/2016

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Australia

United States of America

Study participating centre
Metro Pain Group
Monash House
Clayton Road 271
Clayton
Australia
VIC 3168

Study participating centre
Ochsner Clinical Foundation (Ochsner Health System)
1514 Jefferson Highway
New Orleans, LA
United States of America
70121

Study participating centre
Pain Diagnostics and Interventional Care
301 Ohio River Blvd Suite 203
Sewickley, PA
United States of America
15143

Study participating centre
Swedish Medical Center
801 Broadway, MS 725
Seattle, WA

United States of America
98122

Sponsor information

Organisation
Nevro Corp

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1800 Bridge Parkway
Redwood City
United States of America
CA 94065

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
31/12/2017

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/01/2022	25/03/2022	Yes	No