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A clinical study to evaluate HF10™ therapy in patients with chronic intractable predominant leg pain

Submission date
17/02/2017

Recruitment status
No longer recruiting

Registration date
24/02/2017

Overall study status
Completed

Last Edited
26/10/2021

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
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 in Australian patients with predominant leg pain, as per centers' routine practice.

Who can participate?
Patients aged over 18 with chronic, intractable 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 two leads (which look like very thin wires) into a small area near the spinal cord. Electrical stimulation is delivered through these wires 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 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 10 pain centers across Australia

When is the study starting and how long is it expected to run for?
March 2017 to October 2021

Who is funding the study?
Nevro Corp (USA)

Who is the main contact?
1. Dr Jey Subbaroyan (scientific)
2. Mr Wim Laloo (public)

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CA2016AU PLP

Study information

Scientific Title
A multi-center prospective observational clinical study to evaluate HF10™ therapy in patients with chronic intractable predominant leg pain

Study objectives
The aim of this study is to evaluate and to document the clinical performance of HF10 therapy in patients with chronic intractable predominant leg pain, as per the center's routine practice (on-label use of TGA approved/CE marked device).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bellberry Human Research Ethics Committee, 24/02/2017, ref: 2016-12-871

Study design
Multi-center prospective observational clinical study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

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 1, 3, 6, 9 and 12 months, to complete questionnaires, and to provide feedback on their pain, quality of life, disability, health status, satisfaction and sleep. 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

Primary outcome measure
Responder rate at 3 months (a responder is defined as a subject who experiences ≥50% leg pain reduction compared to baseline as assessed by VAS)

Secondary outcome measures
1. Percentage of subjects with a successful trial phase, defined as at least 50% leg pain reduction as assessed by VAS at the End of Trial phase
2. Change from baseline in mean leg pain, assessed by VAS at End of Trial, 1, 3, 6, 9 and 12 months
3. Change from baseline in mean back pain, assessed by VAS at baseline, End of Trial, 1, 3, 6, 9 and 12 months
3. Percentage change from baseline in mean leg pain, assessed by VAS at End of the Trial, 1, 3, 6, 9 and 12 months
4. Percentage change from baseline in mean back pain, assessed by VAS at End of the Trial, 1, 3, 6, 9 and 12 months*
5. Percentage of subjects who experience at least 50% reduction in leg pain assessed by VAS compared to baseline at End of Trial, 1, 3, 6, 9 and 12 months
6. Percentage of subjects who experience at least 50% reduction in back pain assessed by VAS compared to baseline at End of Trial, 1, 3, 6, 9 and 12 months*
7. Change from baseline in quality of life, assessed by Short-Form Health Survey (SF-12) at 3, 6 and 12 months
8. Change from baseline in disability, assessed by Oswestry Disability Index (ODI) at 3, 6 and 12 months
9. Opioid usage, measured using standard clinical question to the subject and collection via a CRF, at baseline, end of SCS trial period, 1, 3, 6, 9 and 12 months
10. Subject's impression of change in general health status, assessed by the Patient Global Impression of Change instrument (PGIC) at End of Trial, 1, 3, 6, 9 and 12 months
11. Investigator’s impression of change in the subject’s general health status, assessed by the Clinician Global Impression of Change instrument (CGIC) at End of Trial, 1, 3, 6, 9 and 12 months
12. Incidence of unanticipated adverse device effects (UADEs), measured using standard clinical question to the subject and collection via a CRF, at baseline, end of trial, 1, 3, 6, 9 and 12 months
13. Change from baseline in Short-Form McGill Pain Questionnaire (SF-MPQ-2) at 3, 6 and 12 months
14. Participant satisfaction with the therapy, measured using the Subject Satisfaction questionnaire at 3 and 12 months
15. Change from baseline in health status , assessed by EQ-5D-5L at 3, 6 and 12 months
16. Change from baseline in sleep disturbance, assessed by the Pain and Sleep Questionnaire three-item Index (PSQ-3) at End of Trial, 1, 3, 6, 9 and 12 months
17. Work status, measured using the standard clinical question to the subject and collection via a CRF, at baseline and 12 months

(* for subjects with a baseline back pain VAS > 5.0)

Overall study start date
07/10/2016

Completion date

31/10/2021

Eligibility

Key inclusion criteria
1. Predominant leg pain either idiopathic in origin or from failed back surgery syndrome which has been refractory to conservative therapy for a minimum of 3 months
2. Average leg pain intensity of ≥ 5 out of 10 cm on the Visual Analog Scale (VAS) at enrollment
3. Average leg pain intensity > average back pain intensity on the Visual Analog Scale (VAS) by 2 cm at enrollment
4. Neuropathic pain as clinically determined by the investigator
5. On stable pain medications, as determined by the Investigator, for at least 4 weeks prior to the Baseline Visit
6. Be an appropriate candidate for HF10 therapy
7. At least 18 years of age at time of enrollment
8. Willing and capable of giving written informed consent prior to any study -related assessment
9. Was evaluated at the investigational site at least once prior to screen for the pain condition related to the study
10. Willing and able to comply with study-related requirements, assessments and visits
11. Capable of subjective evaluation, able to read and understand English-written questionnaires, and able to read, understand and sign the written inform consent in English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90 study participants with a permanent device implant will be evaluated

Key exclusion criteria
1. A medical condition or pain in other area(s), not intended to be treated with SCS, that could interfere with study assessments, accurate pain reporting, and/or confound evaluation of study endpoints
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 in consultation with a clinical psychologist if applicable
3. 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
4. A visceral pain in the area being treated
5. A current diagnosis of a coagulation disorder, bleeding diathesis, progressive peripheral

vascular disease or uncontrolled diabetes mellitus
6. A diagnosis of scoliosis that precludes lead placement
7. Leg pain that occurs only with weight bearing
8. Benefitting within 30 days prior to enrollment from an interventional procedure and/or surgery to treat back and/or leg pain
9. Existing drug pump and/or SCS system or another active implantable device such as a pacemaker (switched On or Off)
10. Have a condition currently requiring or likely to require diathermy
11. Metastatic malignant disease or active local malignant disease
12. A life expectancy of less than 1 year
13. An active systemic or local infection
14. 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)
15. Within 6 months of enrollment a significant untreated addiction to dependency producing medications or have been a substance abuser (including alcohol and illicit drugs)
16. Concomitantly participating in another clinical study, or planned to be enrolled in another clinical study
17. Involved in an injury claim under current litigation
18. A pending or approved work cover claim

Date of first enrolment
01/03/2017

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
Australia

Study participating centre
Precision Brain, Spine & Pain Centre
Lower Ground
115 Cotham Road
Kew (VIC)
Australia
3101

Study participating centre
Inner West Pain Centre
Suite 211, RPA Medical Centre
100 Carillon Avenue
Newtown (NSW)
Australia
2042

Study participating centre
Holthouse
12/237 Stirling Highway
Claremont (WA)
Australia
6010

Study participating centre
PainMed SA
500 Port Road
Welland (SA)
Australia
5007

Study participating centre
Victoria Pain Specialists
27 Erin Street
Richmond (VIC)
Australia
3121

Sponsor information

Organisation
Nevro Corp

Sponsor details
1800 Bridge Parkway
Redwood City
United States of America
CA94065

Sponsor type
Industry

Website
http://www.nevro.com

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
31/12/2021

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 Jey Subbaroyan

IPD sharing plan summary
Available on request