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The effect of HF10™ Therapy on opioid analgesic use for the treatment of chronic intractable low back and/or radicular leg pain

Submission date
17/09/2018

Recruitment status
No longer recruiting

Registration date
16/10/2018

Overall study status
Completed

Last Edited
17/12/2019

Condition category
Musculoskeletal Diseases

[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:
Long-term opioid use is common in people with chronic pain. This can lead to immune suppression, endocrine suppression, reduced libido, and an overall detrimental effect on the quality of life. These side effects have pushed the need for more appropriate pain management options, such as spinal cord stimulation (SCS). 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). This study will investigate the effect of HF10 Therapy on opioid analgesic pain management in a low back pain and/or leg pain population.

Who can participate?
Adults with chronic intractable low back and/or radicular 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. Following device activation, participants will consult with their doctor to actively work towards reducing their pain medications during the 12 month follow up period. 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?
7 pain centers across Australia

When is the study starting and how long is it expected to run for?
January 2018 to December 2022

Who is funding the study?
Nevro Corp (USA)

Who is the main contact?
Mr Wim Laloo
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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
CA2018AU OR

Study information

Scientific Title
A Prospective Post-market Study to Investigate the Effect of HF10™ Therapy on Opioid Analgesic Use for the Treatment of Chronic Intractable Low Back and/or Radicular Leg Pain

Study objectives
To investigate the effect of HF10 Therapy on opioid analgesic pain management in chronic intractable low back and/or radicular leg pain population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bellberry Limited, 17/09/2018, ref 2018-08-633

Study design
Observational prospective multi-centre cohort study

Primary study design
Observational

Secondary study design
Cohort study

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 low back and/or radicular 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 centre’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. Following device activation, participants will consult with their doctor to actively work towards reducing

their pain medications during the 12 month follow up period. 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
The proportion of subjects who report clinical success with HF10 therapy at the 6-month study visit. Clinical success is denoted by any of the following criteria described on the Opioid Use and Pain Outcome Matrix:
1. Decreased opioids (≥30%)
2. Decrease in predominant pain (≥30%)

Secondary outcome measures
The following will be successively evaluated (hierarchical test approach) in the order shown with a 0.05 significance until statistical significance is not achieved:
1. Proportion of subjects who respond to HF10 therapy, assessed at the baseline and after 6 months by a ≥50% improvement in low back pain or leg pain visual analogue scale (VAS) from the baseline at 6 months
2. Proportion of subjects reporting at least a 30% reduction from baseline in opioid analgesic use as measured by the morphine equivalent daily dose (MEDD) at 6 months
3. Proportion of subjects who respond to HF10 therapy, assessed at the baseline and after 12 months by a ≥50% improvement in low back pain or leg pain VAS from the baseline at 12 months
4. Proportion of subjects reporting at least a 30% reduction from baseline in opioid analgesic use as measured by the morphine equivalent daily dose (MEDD) at 12 months
5. Proportion of subjects that experience at least a 10-point reduction in the Oswestry Disability Index at 12 months
6. Proportion of patients reporting ≥0.100 improvement from the baseline in quality of life, assessed using the EQ-5D-5L at 12 months

Overall study start date
07/01/2018

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Diagnosed with chronic intractable back and/or leg pain
2. 18 years of age or older at time of enrolment
3. Currently taking opioids within a dose range of 15-100 mg/day oral morphine or the equivalent (MEDD)
4. Average back or leg pain intensity of ≥ 5 out of 10 cm on the Visual Analog Scale (VAS) at enrolment
5. Meet the requirements for being an HF10 Therapy trial candidate as per the centers' practice, which includes psychological evaluation
6. Willing and able to complete health questionnaires and pain scales as specified in the protocol

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

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

Key exclusion criteria
1. Plans to enrol in another clinical study during their participation in this study, or are currently enrolled in an interventional clinical study that could interfere in participation in this study or affect the scientific soundness of this study
2. 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 (such as primary headache diagnosis or fibromyalgia)
3. Current addiction to cocaine, opiates, alcohol, or benzodiazepines as determined by the treating physician
4. 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 either the treating physician or a psychologist
5. 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, and/or central deafferentation syndrome
6. Current diagnosis of a coagulation disorder, bleeding diathesis that would put subject at any increased risk of bleeding during SCS procedure, progressive peripheral vascular disease, or uncontrolled diabetes mellitus
7. Diagnosis of scoliosis that precludes lead placement
8. Condition currently requiring or likely to require the use of diathermy
9. Metastatic malignant disease or active local malignant disease
10. Life expectancy of less than 1 year
11. Active systemic or local infection
12. 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)

Date of first enrolment
31/12/2018

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Australia

Study participating centre
Northern Integrated Pain Management
Suite 3, 20 Smith Street,
Charlestown
Australia
NSW 2290

Study participating centre
Interventus Pain Specialists
Suite 20A Level 10
Evan Thomson Building
Chasely Street
AUCHENFLOWER,
Australia
QLD 4066

Study participating centre
Pain Management Unit
The Canberra Hospital,
Building 8, Level 1,
Off Palmer Street Garran,
Woden
Australia
ACT 2606

Study participating centre
Precision Brain and Spine
115 Cotham Road
Kew
Australia
VIC 3101

Sponsor information

Organisation
Nevro Corp

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1800 Bridge Parkway
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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 from the start of 2020
2. Planned publication in a peer-reviewed journal from the end of 2020

Intention to publish date
31/12/2020

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 Adele Barnard

IPD sharing plan summary
Available on request