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A clinical study to evaluate HF10™ therapy in patients with chronic post-surgical shoulder pain

Submission date
03/02/2019

Recruitment status
No longer recruiting

Registration date
01/04/2019

Overall study status
Completed

Last Edited
05/04/2019

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Chronic post-surgical pain (CPSP) is pain that is present for at least 3 to 6 months post-surgery. Post-surgical shoulder pain remains a difficult-to-treat area of pain. Spinal cord stimulation (SCS) is a well-established technique for a particular type of persistent pain involving the nervous system called neuropathic pain, and is well established for treating the back and legs. This study aims to investigate the effect of high-frequency SCS at 10 kHz (HF10 Therapy™) delivered through the Senza system on chronic (long-lasting) shoulder pain after shoulder surgery that has not responded to previous treatment.

Who can participate?
Adults aged 18 years and older who have chronic post-surgical shoulder pain.

What does the study involve?
Participants will receive Spinal Cord Stimulation (SCS) 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, implanted generator. Each participant is followed for 12 months. The participants attend regular clinic visits to complete questionnaires, and to provide feedback on their pain.

What are the possible benefits and risks of participating?
Participants may benefit through relief of 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?
Monash Clinical Research (Australia)

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

Who is funding the study?
Nevro Corp (USA)

Who is the main contact?
Mr Brad Gliner, Nevro Corp

Contact information

Type(s)
Public

Contact name
Mr Brad Gliner

Contact details
Nevro Corp
1800 Bridge Parkway
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United States of America
CA94065

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CA2018AU CPSS

Study information

Scientific Title
A Prospective, Post-market Study to Investigate the Effect of HF10™ Therapy for the Treatment of Chronic Post-Surgical Shoulder Pain

Study objectives
The purpose of this observational study is to document the safety and effectiveness of HF10™ Therapy delivered to the spinal cord in subjects with chronic, focal, neuropathic shoulder pain subsequent to surgery of the shoulder joint.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Application under review, Bellberry Human Research Ethics Committee (Bellberry Office (SA), 123 Glen Osmond Road, Eastwood, Adelaide, South Australia 5063; +61 8 8361 3222; bellberry@bellberry.com.au)

Study design
Single-center prospective post-marketing observational 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 contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Chronic post-surgical shoulder neuropathic 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. 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.

Following device activation, participants are followed for a period of 12 months. The participants attend regular clinic visits, at 1, 3, 6, and 12 months, to complete questionnaires, and to provide feedback on their pain, quality of life, disability, health status and satisfaction. 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
There is no primary endpoint as this is an unpowered study of 10 subjects.

Secondary outcome measures
1. Responder rate at 3 months. A responder is defined as a subject who experiences ≥50% pain reduction compared to Baseline as assessed by the 10-cm pain visual analogue scale (VAS)
2. Percentage of subjects with a successful trial phase. Successful trial phase defined as at least 50% pain reduction as assessed by VAS at the End of Trial phase.
3. Pain at End of Trial, 1-, 3-, 6- and 12-months assessed by VAS
4. Health status at 3-, 6- and 12-months assessed by EQ-5D-5L

Overall study start date
10/10/2018

Completion date
01/09/2022

Eligibility

Key inclusion criteria
1. Chronic post-surgical pain, neuropathic in origin from joint surgery of the shoulder (e.g., arthroscopic stabilization, rotator cuff repair, arthroscopic acromioclavicular joint debridement, subacromial decompression, shoulder joint replacement), which has been refractory to conservative therapy for a minimum of 3 months and is >6 months post-surgery
2. Average pain intensity of ≥5 out of 10 cm on the Visual Analog Scale (VAS) at enrollment
3. Single or bilateral region joint post-surgery pain
4. Aged 18 years or older at time of enrollment
5. Neuropathic pain as clinically determined by the investigator or the DN4 questionnaire.
6. On stable pain medications, as determined by the Investigator, for at least 4 weeks prior to the Baseline Visit
7. Meets the requirements for being an HF10 Therapy trial candidate as per the center's practice which may include psychological evaluation
8. Willing and able to complete health questionnaires and pain scales as specified in the protocol
9. Capable of subjective evaluation, able to read and understand English-written questionnaires, and able to read, understand and sign the written informed consent in English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Prosthesis failure for shoulder joint replacement patients, including, but not limited to structural, material and alignment conditions as determined by a qualified surgeon
2. Has plans to enroll in another clinical study during their participation in this study, or is currently enrolled in an interventional clinical study that could interfere in participation in this study or affect the scientific soundness of this study
3. 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)

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 as determined by the Investigator
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 as determined by the Investigator
7. Any previous history of surgery on the posterior elements (laminectomy, posterior fusion) or clinical back instability with surgically unstable spondylolisthesis that would disrupt/obliterate the posterior epidural space as determined by the Investigator
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

Date of first enrolment
01/03/2019

Date of final enrolment
01/03/2021

Locations

Countries of recruitment
Australia

Study participating centre
Monash Clinical Research
Clayton
Australia
3162

Sponsor information

Organisation
Nevro Corp

Sponsor details
1800 Bridge Parkway
Redwood City
United States of America
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
01/09/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request.

IPD sharing plan summary
Available on request