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Comparison of HF10 therapy combined with Conventional Medical Managment (CMM) to CMM alone in the treatment of chronic back pain

Submission date
21/11/2017

Recruitment status
No longer recruiting

Registration date
27/11/2017

Overall study status
Completed

Last Edited
09/01/2019

Condition category
Injury, Occupational Diseases, Poisoning

[ ] 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 pain is one of the most common and hard to control medical conditions. Low back pain is a major health problem throughout the world and conventional medical and surgical management is often not sufficient for the treatment of chronic pain. Spinal Cord Stimulation (SCS) has been used to treat low back pain in people with continuous or recurring pain following invasive spinal surgery. There is good evidence to recommend SCS in people with back pain without a history of spinal surgery, particularly because SCS is a less invasive and reversible therapy that may provide greater long-term benefits than more invasive surgical approaches. This study is being conducted to document the safety, clinical effectiveness and cost-effectiveness of high-frequency SCS at 10 kHz (HF10 Therapy™) delivered through the Senza system in subjects with chronic refractory back pain who are not considered candidates for spine surgery. The subjects will be either allocated to HF10 Therapy or Conventional Medical Managment (CMM). This study aims to further investigate the pain relief achieved when using Nevro's Senza System to treat low back pain in patients who have not undergone invasive spinal surgery compared to the CMM group.

Who can participate?
Adults aged 18 and older who have chronic lower back pain.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive Spinal Cord Stimulation (SCS). Those in the second group receive medical pain management 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 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 from both treatments (HF10 therapy and CMM) 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?
1. Technical University of Munich (Germany)
2. Guy's & St. Thomas's NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
December 2016 to December 2020

Who is funding the study?
Nevro Corp (USA)

Who is the main contact?
Mr Brad Gliner

Contact information

Type(s)
Public

Contact name
Mr Brad Gliner

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Nevro Corp
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CA2017 SENZA-NSRBP

Study information

Scientific Title
A multi-center, prospective, pragmatic, randomized, controlled clinical trial to compare HF10 therapy to Conventional Medical Management in the treatment of Non-Surgical Refractory Back Pain

Acronym
SENZA-NSRBP

Study objectives
This study is being conducted to document the safety, clinical effectiveness and cost-effectiveness of high-frequency SCS at 10 kHz (HF10 Therapy™) delivered through the Senza system in subjects with chronic refractory back pain (with or without leg pain) who are not considered candidates for spine surgery (i.e., chronic non-surgical refractory back pain).

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East - York Research EC, 08/08/2017, ref: 224762

Study design
Multi-center prospective randomised study to compare the two treatment groups

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Chronic non-surgical refractory back pain

Interventions
Participants are randomly allocated in a 1:1 ratio to either the control or the intervention group:

Those in the intervention group receive the HF10 spinal cord stimulation therapy. They undergo Spinal Cord Stimulation (SCS) at 10 kHz (HF10 Therapy). 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.

The control group received the Conventional Medical Management (CMM). CMM is the standard treatment provided for chronic back pain patients if not treated with a spinal cord stimulation system – Active Comparator is HF10+CMM. Device is HF10 therapy (Senza 10kHz Spinal Cord Stimulation).

Each participant is followed for 12 months. The participants attend regular clinic visits to complete questionnaires, and to provide feedback on their pain. The treatment for both group is expected to last a total of 12 months.

Intervention Type
Device

Primary outcome measure
Responder rates is measured using the visual analog scale (VAS) (as defined by at least a 50% reduction in pain) at 3 months.

Secondary outcome measures
1. Successful back pain relief is measured using the visual analog scale (VAS) at 1, 3, 6, 9 and 12 months
2. Percentage of patients who experience at least 50% reduction in pain intensity is measured using the VAS at 1, 3, 6, 9 and 12 months
3. Back pain intensity is measured using VAS at baseline, 1, 3, 6, 9 and 12 months
4. Percentage of participants who experience a back pain intensity score of ≤2.5 cm as measured using the VAS scale at 1, 3, 6, 9 and 12 months
5. Quality of life is measured using EQ-5D questionnaire at 3, 6 and 12 months
6. Health economic outcomes are measured using clinic visits, incidence of adverse events, EQ-5D at 1, 3, 6, 9 and 12 months

Overall study start date
05/12/2016

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Have been diagnosed with chronic, refractory axial low back pain with a neuropathic component
2. Have failed conventional medical treatments
3. Have not had any surgery for back or leg pain, or any surgery resulting in back or leg pain
4. Demonstrating multi-level Degenerative Disc Disease and no current indication for referral for back surgery
5. Considering daily activity and rest, have average back pain intensity of ≥ 5 out of 10 cm on the Visual Analog Scale (VAS) at enrollment
6. Average back pain intensity greater than average leg pain intensity on the Visual Analog Scale (VAS) at enrollment
7. Be on stable pain medications, as determined by the Investigator
8. Be 18 years of age or older at the time of enrollment
9. Be willing and capable of giving informed consent
10. Be willing and able to comply with study-related requirements, procedures, and visits
11. Be capable of subjective evaluation, able to read and understand written questionnaires in the local language and are able to read, understand and sign the written inform consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Have a diagnosed back condition with inflammatory causes of back pain, serious spinal pathology and/or neurological disorders
2. Have a medical condition or pain in other area(s), not intended to be treated in this study
3. Any diagnosis or known condition that can impact reporting of study outcomes as determined by the Investigator
4. Have significant clinically mechanical spine instability
5. Be benefitting within 30 days prior to enrollment from an interventional procedure to treat back and/or leg pain
6. Have an opioid addiction or drug seeking behavior as determined by the Investigator
7. Have an existing drug pump and/or SCS system or another active implantable device such as a pacemaker
8. Have prior experience with neuromodulation devices
9. Have a condition currently requiring or likely to require the use of diathermy or MRI that is inconsistent with Senza system guideline in the Physician's Manual
10. Have metastatic malignant disease or active local malignant disease
11. Have a life expectancy of less than 2 years
12. Have an active systemic or local infection
13. Be pregnant (participants of child-bearing potential that are sexually active must use a reliable form of birth control)
14. 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)
15. Be concomitantly participating in another clinical study
16. Be involved in an injury claim under current litigation
17. Have a pending or approved worker's compensation claim

Date of first enrolment
31/10/2017

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Austria

England

Germany

Netherlands

United Kingdom

Study participating centre
Klinikum rechts der Isar der Technischen Universität München
Munich
Germany
81675

Study participating centre
Guy's & St. Thomas's NHS Foundation Trust
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Nevro Corp

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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
The current publication plans for the current study are unknown and will be made available at a later date.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date