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A clinical study to evaluate the Senza™ spinal cord stimulation system in patients with pain from vascular disease

Submission date
06/12/2017

Recruitment status
No longer recruiting

Registration date
14/12/2017

Overall study status
Completed

Last Edited
13/12/2017

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Worldwide, one in five people suffer from moderate to severe chronic pain. Of these, one in three is unable or less able to maintain an independent lifestyle due to pain. Between 50-60% of people with chronic pain are less able or even unable to exercise, sleep normally, perform household chores, attend social activities, drive a car, or walk. Critical limb ischemia is a severe obstruction of the blood vessels which markedly reduces blood flow to the hands, feet and legs, leading not only to compromised patient activity and function but also ongoing chronic pain. Spinal cord stimulation (SCS) is a treatment that masks pain signals before they reach the brain using a small device implanted in the body that delivers electrical pulses to the spinal cord. Traditional spinal cord stimulation has been used for several decades to treat the pain resulting from the ischemia. HF10 therapy is a new form of SCS that has demonstrated better long-term relief of chronic low back and leg pain in a large study. The aim of this study is to investigate the effect of HF10 therapy applied at two different spinal locations to relieve chronic pain due to critical limb ischemia.

Who can participate?
Patients aged over 18 with chronic lower limb pain from vascular disease

What does the study involve?
Participants undergo a trial of HF10 therapy delivered at different locations in the spinal column. Successfully trialed participants get a permanent device implanted. Following device implant, the participant is randomly allocated to one of two orders of stimulation. If the participant experiences sufficient pain reduction they continue in the study, programmed with their preferred settings. At 3 months, the participant is again randomly allocated to two orders of stimulation. At the end of this test they are programmed to their preferred setting to provide the greatest pain relief. Participants are followed up to assess their pain levels at 6 and 12 months.

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 have a spinal stimulation device in place apply.

Where is the study run from?
Seacroft Hospital (UK)

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

Who is funding the study?
Nevro Corp (USA)

Who is the main contact?
Kerry Bradley

Contact information

Type(s)
Public

Contact name
Mr Kerry Bradley

Contact details
Nevro Corp
1800 Bridge Parkway
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Additional identifiers

Protocol serial number
CA2016OUS PVD2

Study information

Scientific Title
Prospective feasibility clinical single-center trial of the Senza™ spinal cord stimulation (SCS) system in the treatment of chronic intractable pain from vascular disease

Study objectives
The aim of this study is to assess the impact of 10 kHz electrical stimulation (HF10™ therapy) delivered within different locations of the spinal column in subjects with chronic, intractable unilateral lower limb pain from vascular disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)

North East - York Research Ethics Committee, 26/07/2017, REC ref: 17/NE/0225

Study design
Single-center prospective randomized feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic intractable pain from vascular disease

Interventions
Eligible subjects will undergo a trial of Spinal Cord Stimulation (SCS) at 10kHz (HF10 therapy) delivered within different locations in the spinal column. Successfully trialed subjects will get a permanent device implanted. Following device implant, the patient will be randomized using envelopes to one of two orders of stimulation. If the subject experiences sufficient pain reduction they will continue in the study, programmed with their preferred setting. At 3 months, the subject will undergo again randomization to two orders of stimulation. At the completion of this evaluation will be programmed to their preferred setting to provide the greatest pain relief. Subjects will be followed up at 6 and 12 months.

Intervention Type
Device

Primary outcome(s)
The proportion of subjects who achieve 30% or greater pain reduction based on NRS pain scores from baseline during the Later Evaluation Period at 3 months for any lead placements

Key secondary outcome(s))
1. Responder rate as measured by NRS at 3, 6 and 12 months
2. Proportion of subjects who prefer a specific stimulation setting at 3 months
3. Change in pain (NRS) as measured by NRS from baseline at 3, 6 and 12 months
4. Change in claudication distance as measured by distance walked from baseline at 3, 6 and 12 months
5. Change in PPG Toe pressure as measured by systolic pressures at the toe from baseline at 3, 6 and 12 months
6. Change in TcPO2 measurements as measured by transcutaneous oxygen pressure from baseline at 3, 6 and 12 months
7. Impressions of change, as measured by CGIC and PGIC questionnaire at 3, 6 and 12 months

Completion date
01/04/2020

Eligibility

Key inclusion criteria

1. Have been diagnosed with chronic, intractable ischemic pain secondary to vascular disease with non-reconstructable, predominantly unilateral critical limb ischemia, with possible sub-diagnoses including (but not limited to) peripheral arterial disease, peripheral vascular disease, and diabetic peripheral neuropathy
2. Considering daily activity and rest, have average lower limb pain intensity of ≥ 5 out of 10 on the Numerical Rating Scale (NRS) at enrollment
3. Have limb ischemia condition rated with Fontaine class IIb or III
4. Have no ulcers
5. Have TcPO2 > 10 mm of Hg in the affected limb
6. Be on stable pain medications, as determined by the Investigator, for at least 28 days prior to enrolling in this study and be willing to stay on those medications
7. Be 18 years of age or older at the time of consent
8. Be willing and able to comply with study-related requirements, procedures, and visits
9. Be capable of subjective evaluation, able to read and understand written questionnaires, and are able to read, understand and sign the written informed consent
10. Have adequate ability to use a patient programmer and recharger as determined by the Investigator

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Have undergone destructive sympathectomy as treatment for pain due to chronic critical limb ischemia
2. 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 (such as primary headache diagnosis and fibromyalgia)
3. 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
4. Have a current diagnosis of a progressive neurological disease such as multiple sclerosis, chronic inflammatory demyelinating polyneuropathy, rapidly progressive arachnoiditis, brain or spinal cord tumor, and/or central deafferentation syndrome
5. In the target lower limb, have previous major amputation, lesions with wet gangrene, or deep infections.
6. Have a current diagnosis of a coagulation disorder, such as bleeding diathesis that would put patient at any increased risk of excessive bleeding during SCS procedure, as determined by the

investigator(s)
7. Be currently treated with anticoagulation therapy which cannot be safely managed temporarily for the duration of the SCS trial and implant procedures, as determined by the investigator(s)
8. Any previous history of back surgery that would inhibit access to epidural space for lead placement targets
9. Be benefitting from an interventional procedure and/or surgery to treat chronic, intractable unilateral lower limb pain from vascular disease (Subjects should be enrolled at least 30 days from last benefit)
10. Have an existing drug pump and/or another active implantable device (switched On or Off) such as a pacemaker or other SCS devices. Additionally, have previously trialed and/or been implanted with an SCS device.
11. Have a condition currently requiring or likely to require the use of MRI of the trunk or therapeutic diathermy
12. Have metastatic malignant disease or active local malignant disease
13. Is believed to or has prognosis of a life expectancy less than 1 year
14. Have an active systemic or local infection
15. Be 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)
16. 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)
17. Be concomitantly participating or planned to be participating in another clinical study
18. Be involved in an injury claim under current litigation

Date of first enrolment
01/12/2017

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Seacroft Hospital
Leeds Teaching University Hospital NHS Trust
Leeds
United Kingdom
LS14 6UH

Sponsor information

Organisation
Nevro Corp

ROR
https://ror.org/02xcxe208

Funder(s)

Funder type
Industry

Funder Name
Nevro Corp.

Results and Publications

Individual participant data (IPD) sharing plan
The 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes