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HF10™ spinal cord stimulation in the treatment of refractory chronic migraine

Submission date
06/07/2015

Recruitment status
No longer recruiting

Registration date
06/07/2015

Overall study status
Completed

Last Edited
13/03/2020

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A migraine is a condition where sufferers experience a severe headache felt as a throbbing pain in the front or side of the head. Sufferers may also feel sick, vomit and become sensitive to light or sound. Treatments include painkillers, triptans (drugs that may help reverse changes in the brain that can cause migraine) and drugs that help with nausea and vomiting. Spinal cord stimulation systems can be useful in treating the pain caused by migraines. These devices sent small electrical fields to the spinal cord and mask areas of pain by altering the pain messages that the body sends to the brain. The purpose of this study is to assess how safe and effective the Nevro Senza spinal cord stimulation (SCS) system is in patients with difficult to manage chronic migraine. Patients who are suffering from chronic migraine that has not responded to established therapies, can be enrolled in the study.

Who can participate?
Patients aged at least 18 who are suffering from chronic migraine that has not responded to established therapies.

What does the study involve?
Each patient taking part in the study is implanted with a Senza SCS system. 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, in an attempt to provide pain relief, by a small, battery-operated, rechargeable SCS implanted generator. Each patient is followed for 12 months after device activation. During this period, the effect of SCS on the number of headaches experienced and how bad they are is monitored by using a headache diary.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Guy's and St. Thomas Hospital, London (UK)

When is the study starting and how long is it expected to run for?
February 2015 to December 2017

Who is funding the study?
Nevro Corp. (USA)

Who is the main contact?
Dr Adnan Al-Kaisy

Contact information

Type(s)
Scientific

Contact name
Dr Adnan Al-Kaisy

Contact details
Guy's and St Thomas' Hospital
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United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CA2014OUS CM

Study information

Scientific Title
HF10™ spinal cord stimulation in the treatment of refractory chronic migraine: an open-label, prospective, single arm, feasibility study

Acronym
N/A

Study objectives
The purpose of this study is to assess the safety and effectiveness of HF10™ electrical stimulation delivered to the spinal cord in subjects with refractory chronic migraine.

Ethics approval required
Old ethics approval format

Ethics approval(s)

NRES Committee North East - York, 26/05/2015, ref: 15/NE/0168

Study design
Open-label, prospective, single arm, feasibility 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
Refractory chronic migraine

Interventions
This is an open label, prospective, feasibility study to collect data on HF10 spinal cord stimulation (SCS) for the treatment of refractory chronic migraine. HF10 therapy will be delivered using the Senza System. The use of the Senza System for treatment of chronic migraine is investigational. Subjects will be consented, enrolled and eligibility criteria checked. The study will run in two stages:
Stage 1: If subject is eligible, subject will proceed with Senza system implantation. After system implant outcomes will be assessed via standardized assessments at 4, 8, 12, 24 and 52 weeks after device activation.
Stage 2: After the 52 weeks post-device activation visit, subjects will be followed for safety monitoring every 6 months until the device is CE marked for chronic migraine or the device is explanted for medical reasons or device end of life, whichever occurs first.

Intervention Type
Device

Primary outcome measure
1. Primary Effectiveness Measure: Change from baseline in number of moderate-to-severe headache days at 12 weeks post-device activation
2. Primary Safety Measure: Incidence of unanticipated adverse device effects (UADEs) at 12 weeks post-device activation

Secondary outcome measures
1. Change from Baseline in number of moderate-to-severe headache days at 24 and 52 weeks post-device activation
2. Change from Baseline in number of migraine days at 12, 24 and 52 weeks post-device activation

3. Responder rate (Responder is defined by at least a 30% reduction in headache days per month) at 12, 24 and 52 weeks post-device activation
4. Conversion from chronic to episodic migraine at 12, 24 and 52 weeks post-device activation
5. Change from Baseline in Migraine Disability Assessment (MIDAS) score at 12, 24 and 52 weeks post-device activation
6. Change from Baseline in Headache Impact as measured by Headache Impact Test (HIT-6) at 12, 24 and 52 weeks post-device activation
7. Change from Baseline in quality of life as measured by Migraine-Specific Quality of Life Questionnaire (MSQ) at 12, 24 and 52 weeks post-device activation
8. Change from Baseline in abortive headache medication intake at 12, 24 and 52 weeks post-device activation
9. Assessment of subject's satisfaction with therapy at 12, 24 and 52 weeks post-device activation
10. Subject’s impression of change in quality of life as measured by the Patient Global Impression of Change (PGIC) questionnaire at 12, 24 and 52 weeks post-device activation
11. Investigator’s impression of change in quality of life as measured by the Clinician Global Impression of Change (CGIC) questionnaire at 12, 24 and 52 weeks post-device activation
12. Incidence of adverse events

Overall study start date
26/02/2015

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Be 18 years of age or older at the time of enrollment.
2. Have been diagnosed with chronic migraine (CM) as per ICHD-2R criteria for at least 6 months as defined by the following:
2.1. Headache on ≥ 15 days/month for at least 3 months.
2.2. At least five attacks fulfilling criteria for migraine without aura (ICHD-2 1.1).
2.3. On ≥ 8 days/month for at least 3 months headache has fulfilled C1 and / or C2 below:
2.3.1. Has at least two of 2.3.1.1-2.3.1.4 (below):
2.3.1.1. Unilateral location
2.3.1.2. Pulsating quality
2.3.1.3. Moderate or severe pain intensity
2.3.1.4. Aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs) and at least one of 2.3.1.4.1. or 2.3.1.4.2. (below):
2.3.1.4.1. Nausea and/or vomiting
2.3.1.4.2. Photophobia and phonophobia
2.3.1.2. Treated and relieved by triptan(s) or ergot before the expected development of C1 above.
2.3.2. No medication overuse and not attributed to another causative disorder
3. Are refractory to conventional pharmacological CM treatment as defined by the failure to respond, or the intolerance, to at least 3 prophylaxis therapies (of which one is topiramate if not contraindicated).
4. Have failed botulinum toxin type A treatment, defined as less than a 30% reduction in headache days per month after two treatment cycles, at least 3 months apart, with the last treatment minimum 3 months ago

5. Are on optimal and stable CM prophylaxis therapy for at least 2 months.
6. Developed CM before the age of 60
7. Be an appropriate candidate for cervical SCS and for the surgical procedures required in this study based on the clinical judgment of the implanting physician
8. Be willing and able to comply with study-related requirements, procedures, and visits and to keep headache diaries
9. Be capable of subjective evaluation, able to read and understand English-written questionnaires, and are able to read, understand and sign the written inform consent in English
10. Have adequate cognitive ability to use a patient remote control and recharger as determined by the Investigator

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Up to 20 subjects with primary safety and effectiveness data at 12 weeks

Key exclusion criteria
1. 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
2. Have a contraindication to the cervical placement of SCS leads as determined by the investigator.
3. Have a PHQ-9 score of more than 19
4. Have previously diagnosed untreated severe psychiatric disorder(s)
5. Have a known history or suspicion of substance abuse or addiction (including alcohol and illicit drugs) as determined by the investigator
6. Have a current diagnosis of a progressive neurological disease such as multiple sclerosis, chronic inflammatory demyelinating polyneuropathy, severe arachnoiditis, severe peripheral neuropathy, brain or spinal cord tumor, central deafferentation syndrome, Complex Regional Pain Syndrome, acute herniated disc, severe cervical spinal stenosis or other as determined by the investigator
7. Have a current diagnosis of a coagulation disorder, bleeding diathesis that would put patient at any increased risk of bleeding during SCS procedure, progressive peripheral vascular disease or uncontrolled diabetes mellitus
8. Have an existing drug pump and/or another active implantable device (switched On or Off) such as a pacemaker or other SCS devices
9. Non-invasive neuromodulation is being used or planned
10. Previous exposure to any implantable neurostimulation device
11. Alternative therapy to treat migraine is being used or planned (e.g. acupuncture, acupressure, biofeedback, homeopathy)
12. Have a condition currently requiring or likely to require the use of MRI or diathermy

13. Have metastatic malignant disease or active local malignant disease
14. Have a life expectancy of less than 1 year
15. Have an active systemic or local infection
16. Be pregnant or breast-feeding (Female subjects of child-bearing potential must have a HCG negative blood serum test prior to implant and must be willing to use an adequate method of birth-control for the duration of the study)
17. Be concomitantly participating or planned to be participating in another clinical study
18. Have a pending or approved worker's compensation claim, and an ongoing planned litigation related to work

Date of first enrolment
15/07/2015

Date of final enrolment
15/07/2016

Locations

Countries of recruitment
United Kingdom

Study participating centre
Guy's and St. Thomas Hospital
Westminster Bridge Road
London
United Kingdom
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Sponsor information

Organisation
Nevro Corp.

Sponsor details
4040 Campbell Avenue
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Menlo Park
United States of America
94025

Sponsor type
Industry

ROR
https://ror.org/02xcxe208

Funder(s)

Funder type
Industry

Funder Name
Nevro Corp. (USA)

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2016	13/03/2020	Yes	No
HRA research summary			28/06/2023	No	No