

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

<b>Submission date</b> 06/07/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/07/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/03/2020	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> 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 send 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  
Westminster Bridge Road  
London  
United Kingdom  
SE17EH

## Additional identifiers

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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(s)**

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

## **Key secondary outcome(s)**

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

**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  $\geq$  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  $\geq$  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 informed 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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

## Sponsor information

**Organisation**  
Nevro Corp.

**ROR**  
<https://ror.org/02xcxe208>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Nevro Corp. (USA)

## Results and Publications

**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?
<a href="#">Results article</a>	results	01/12/2016	13/03/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No