# 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	<b>Recruitment status</b> No longer recruiting	Prospectively registered
		Protocol
Registration date 27/11/2017	Overall study status Completed	Statistical analysis plan
		☐ Results
Last Edited	Condition category	Individual participant data
09/01/2019	Injury, Occupational Diseases, Poisoning	<ul><li>Record updated in last year</li></ul>

## 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

#### Contact details

Nevro Corp 1800 Bridge Parkway Redwood City United States of America CA94065

## 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  $\leq$ 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  $\geq$  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** 

## 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

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