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HF10 therapy for the treatment of chronic pain resulting from spinal cord injury

Submission date
26/10/2016

Recruitment status
No longer recruiting

Registration date
28/10/2016

Overall study status
Completed

Last Edited
17/12/2019

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Spinal Cord Injury (SCI) is an injury to the spinal cord which temporarily or permanently affects the motor (movement), sensory or autonomic (unconscious) functions. SCI is a broad term, which includes both traumatic and non-traumatic causes as well cauda equina lesions (a rare disorder where the nerves at the end of the spinal cord are compressed). In the UK, approximately 700 people sustain a new SCI each year. These injuries are associated with serious damage to the nervous system, and can result in paralysis or death. Around 40-50% of SCI patients suffer from neuropathic pain (pain caused by the nervous system). Neuropathic pain in SCI is constant and often unresponsive to available pain treaments. A treatment called spinal cord stimulation (SCS) systems can be useful in treating the pain caused by SCI. This is where an implanted device sends small electrical fields to the spinal cord, masking areas of pain by altering the pain messages that the body sends to the brain. The aim of this study is to evaluate the safety and effectiveness of a SCS treatment called HF10 in alleviating long-term neuropathic pain in patients with SCI by following patients who have a HF10 device implanted as part of their usual care.

Who can participate?
Patients aged over 18 with a spinal cord injury of at least 2 years

What does the study involve?
Participants undergo a trial of Spinal Cord Stimulation (SCS) at 10 kHz (HF10 Therapy) as per the center's usual practice. Successfully trialed participants get a permanent device implanted as per center's routine clinical 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, 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. 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 the SCS system 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?
South Tees Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2016 to December 2018

Who is funding the study?
Nevro Corp (USA)

Who is the main contact?
1. Professor Sam Eldabe (scientific)
2. Mr Wim Laloo (public)

Contact information

Type(s)
Scientific

Contact name
Prof Sam Eldabe

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South Tees Hospitals NHS Foundation Trust
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Type(s)
Public

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Additional identifiers

Protocol serial number
CA2016OUS SCI

Study information

Scientific Title
HF10 therapy for the treatment of chronic pain resulting from spinal cord injury

Study objectives
The aim of this study is to evaluate the safety and effectiveness of HF10 therapy for the alleviation of chronic neuropathic pain in patients with an incomplete or complete spinal cord injury.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS - Health Research Authority - North East - York Research Ethics Committee, 26/10/2016, ref: 16/NE/0315

Primary study design
Observational

Study design
Single-centre open label post-market (on-label) cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Spinal cord injury

Interventions
As part of their standard care, participants undergo a trial (temporary evaluation period) of Spinal Cord Stimulation (SCS) at 10 kHz (HF10 Therapy) as per the center's usual practice and following this, those for whom the trial treatment was successful have a permanent device implanted as per center's routine clinical practice.

Following device activation, participants are followed for a period of 12 months. The participants attend regular clinic visits, at 1, 3, 6, 9 and 12 month, to complete questionnaires, and to provide feedback on their pain, disability, health status, mental state and sleep. At these visits, the physicians will take assessments from the participants such as neurological testing, spasticity, disability, health status, medication usage and side effects (if any).

Intervention Type
Device

Primary outcome(s)
1. Targetted pain area directly related to SCI is measured using the Visual Analog Scale (VAS) at baseline, end of SCS trial period, 1, 3, 6, 9 and 12 month visits
*target pain area: neuropathic pain following SCI (at-level and below-level)
2. Neurological level and/or sensorimotor state is measured using the ASIA Impairment Scale at baseline, 3, 6 and 12 months
3. Neurological pain is measured using the Douleur Neuropathique 4 (DN-4) questionnaire at baseline, end of SCS trial period, 3, 6 and 12 month
4. Spasticity is measured using the Modified Ashworth Scale and Penn Spasm Frequency Scale at

baseline, end of SCS trial period, 3, 6, 9 and 12 months
5. Disability is measured using the Spinal Cord Independence Measure (SCIM) at baseline, end of SCS trial period, 3, 6 and 12 months
6. Health status is measured using the European Quality of Life-5 Dimensions (EQ-5D-5L) questionnaire at baseline, v, 3, 6, 9 and 12 months
7. General state of health is measured using the Patient Global Impression of Change (PGIC) instrument at the end of SCS trial period, 1, 3, 6, 9 and 12 months
8. General state of health is measured using the Clinician* Global Impression of Change (CGIC) instrument at the end of SCS trial period, 1, 3, 6, 9 and 12 months
*Clinician: both pain physician and SCI specialist to complete
9. Depression is measured using the Beck Depression Inventory II (BDI-II) at baseline, end of SCS trial period, 3, 6 and 12 months
10. Sleep disturbance is measured using the Pain and Sleep Questionnaire three-item Index (PSQ-3) at baseline, end of SCS trial period, 3, 6, 9 and 12 months
10. Medication usage is observed at baseline, end of SCS trial period, 3, 6, 9 and 12 months
11. Participant satisfaction with the therapy is measured using the Subject Satisfaction questionnaire at 3, 6 and 12 months
12. Incidence of unanticipated adverse device effects (UADEs) is observed at baseline, end of trial, 3, 6, 9 and 12
13. Pain treatment (only applicable for Trial failures) is observed using the Pain Treatment questionnaire at 12 months

Key secondary outcome(s)
No secondary outcome measures

Completion date
01/05/2020

Eligibility

Key inclusion criteria
1. A spinal cord injury (complete or incomplete lesion) of at least 2 years
2. Injury at cervical/thoracic/lumbar/sacral level
3. A disability grade on the American Spinal Injury Association (ASIA) Impairment Scale (AIS) of A, B, C,D or E as determined by a qualified examiner
4. Neuropathic pain as clinically determined by the investigator
5. Average pain intensity for the target pain area of ≥ 5 out of 10 cm on the Visual Analogue Scale (VAS) at enrollment when the patient is taking medication
6. Stable chronic pain for at least 3 months
7. Refractoriness to pain treatment as determined by the Investigator1 (which can include medication and/or other treatment modalities)
8. On stable pain medications, as determined by the Investigator1, for at least 4 weeks prior to the Baseline Visit
9. An appropriate candidate for HF10™ Spinal Cord Stimulation as determined by the Investigator
10. An appropriate candidate for the surgical procedures required in this study based on the clinical judgment of the implanting physician and if applicable per the local regulations
11. An adult (≥ 18 years of age) at time of enrollment
12. Evaluated at the investigational site at least once prior to screen for the pain condition related to the study
13. Willing and capable of giving written informed consent prior to any investigational related procedure (if not able to write consent will happen through legal or personal representative)

14. Willing and able to comply with study-related requirements, assessments and visits
15. Capable of subjective evaluation, able to read and understand written questionnaires, and are able to read, understand and sign the written inform consent (see Inclusion criterion 13, legal /personal representative)
16. Adequate cognitive ability and sufficient support (e.g. caregiver) to use a patient external trial stimulator, recharger and patient remote as determined by the Investigator

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
21

Key exclusion criteria
1. 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, as determined by the investigator in consultation with a clinical psychologist
2. A current diagnosis of a progressive neurological disease such as multiple sclerosis, inflammatory, infective, vascular, demyelinating polyneuropathy, rapidly progressive arachnoiditis, rapidly progressive diabetic peripheral neuropathy, brain or spinal cord tumor
3. An invalid AIS (e.g. ASIA motor exam not obtainable)
4. A current diagnosis or condition such as a coagulation disorder, bleeding diathesis, platelet dysfunction, progressive peripheral vascular disease or uncontrolled diabetes mellitus that presents excess risk for performing the procedure as determined clinically by the investigator
5. A diagnosis that precludes lead placement (e.g. severe scoliosis)
6. Radiographic evidence of spinal instability requiring fusion as determined by the Investigator
7. Previous and/or current experience with drug pump and/or neurostimulator or another active implantable device such as a pacemaker
8. A condition currently requiring or likely to require the use of MRI of the trunk
9. Metastatic malignant disease or active local malignant disease
10. A life expectancy of less than 1 year
11. An active systemic or local infection
12. 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)
13. Within 6 months of enrollment a significant untreated addiction to dependency producing medications or have been a substance abuser (including alcohol and illicit drugs)
14. Benefitting within 30 days prior to enrollment from an interventional procedure and/or surgery to treat the targeted pain area

15. Concomitantly participating in another clinical study, or planned to be enrolled in another clinical study
16. Involved in an injury claim under current litigation
17. A pending worker's compensation claim as determined by the Investigator

Date of first enrolment
01/12/2016

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

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 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No