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SenzaTM Spinal Cord Stimulation System for the treatment of chronic back pain

Submission date	Recruitment status	[_] Prospectively registered
12/10/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/10/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/07/2019	Signs and Symptoms	

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 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.

Who can participate?
Eligible participants will have experienced chronic low back pain for at least 6 months and for whom conventional medical management, such as physical therapy or minimally invasive interventions, has not proven effective.

What does the study involve?
All participants will have a trial phase period of stimulation with the Senza System of a minimum of 7 days and a maximum of 30 days to determine if they will respond to the treatment. If the treatment is successful and satisfactory pain relief is achieved, a permanent Implantable Pulse Generator (IPG) will be implanted. Participants who receive the permanent system will be required to attend follow-ups for 12 months following implantation.

What are the possible benefits and risks of participating?
Possible benefits include pain relief and improvement in quality of life. Risks to participants are the same as for all SCS devices. These could include surgical complications, increased pain in the areas being treated, pain in other areas, uncomfortable stimulation and allergy to medical device materials. The device or its components may malfunction, requiring surgical revision of the leads or IPG.

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

When is the study the starting and how long is it expected to run for?
The study began in April 2012 will end in March 2014.

Who is funding the study?
Nevro Corp (CA, USA)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CA2011 VB UK

Study information

Scientific Title
Evaluation of the SenzaTM Spinal Cord Stimulation System for the treatment of chronic back pain in subjects without prior spinal surgery

Study objectives
The purpose of this study is to evaluate the Senza System for the treatment of symptoms of chronic low back pain in subjects with no history of invasive spine surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)
NRES Committee North East - Northern and Yorkshire, 12/04/2012, ref: 11/NE/0047

Study design
Single-center single-arm open-label observational study

Primary study design
Observational

Secondary study design
Non-randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic low back pain in subjects who have not had spinal surgery

Interventions
Spinal Cord Stimulation with Nevro's Senza System

This is a single center, open label, prospective study to evaluate the effectiveness of the Senza System in subjects with chronic low back pain who have not had invasive spinal surgery. Subjects meeting the eligibility criteria will be consented, enrolled, and will undergo a baseline evaluation. All subjects will have a Trial Phase period of stimulation of a minimum of 7 days and a maximum of 30 days to determine if they will respond to therapy.

If the subject has a 50% or greater pain reduction in back pain based on VAS at the end of Trial Phase, they are eligible for permanent implant for the device system. Treating physician will also assess adverse events, subject's tolerance of the device, functional changes, and pain medication use during the Trial Phase before the decision is made to proceed with permanent implant.

Subject will be assessed 12 months after activation of the permanent device. Pain, functional changes and medication usage will be asessed at 1, 3, 6, 9 and 12 months after permanent device activation.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Comparison of percentage change from Baseline in back pain (as measured by VAS) at 1, 3, 6, 9 and 12 months.

Secondary outcome measures
1. Comparison of percentage change from Baseline in leg pain (as measured by VAS) at 1, 3, 6, 9 and 12 months
2. Comparison of change from Baseline in functional changes as measured by the Oswestry Disability Index at 3, 6, 9, and 12 months
3. Comparison of change from Baseline in quality of life as measured by SF-36 at 3, 6, 9 and 12 months
4. Comparison of change from Baseline in quality of life as measured by EQ-5D at 3, 6, 9 and 12 months
5. The change in work status from Baseline to follow-ups at 3, 6, 9, and 12 months
6. Change from Baseline in sleep disturbance at 1, 3, 6, 9, and 12 months
7. Paresthesia generated by the stimulator at Post-Permanent Device Activation
8. Adverse events collected during the study at all visits
9. The percentage subjects who experience at least 50% reduction in pain due to SCS therapy (as assessed by VAS) for back pain at 3, 6 and 12 months
10. Percentage change from Baseline in back and leg pain (as assessed by Subject Diary VAS) at 1, 3, 6, 9 and 12 months
11. Change from Baseline in pain and opioid medication usage
12. To learn about the subjects clinical trial experience through videotaping
13. To summarize the subjects global impression of change
14. To summarize the subjects satisfaction with the Senza System
15. To summarize subjects willingness to recommend to another subject with same condition

Overall study start date
19/04/2012

Completion date
31/03/2014

Eligibility

Key inclusion criteria
1. Age greater than 18 years, less than 65 years old
2. Low back pain for more than 6 months having failed conservative treatment (e.g., physical therapy, multiple facet joint injections)
3. Low back pain intensity ≥5 out of 10 cm on the Visual Analog Scale (VAS) at enrollment
4. Low back pain predominates over any radicular pain (VAS back pain 2 points or more greater than VAS leg pain)
5. Degenerative disc disease confirmed by imaging or internal disc disruption as confirmed by discography
6. On stable pain medications, as determined by the Investigator, for at least 28 days prior to enrolling in this study and not change medication dosage without consulting Investigator
7. Legally able to provide informed consent
8. Able to comply with study-related requirements, procedures and visits

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20 with permanent implants

Total final enrolment
21

Key exclusion criteria
1. Had previous spinal fusion surgery
2. A current diagnosis of a progressive neurological disease such as multiple sclerosis, chronic inflammatory demyelinating polyneuropathy, rapidly progressive arachnoiditis, rapidly progressive diabetic peripheral neuropathy, brain or spinal cord tumor, or severe/critical central or foraminal spinal stenosis
3. Mechanical spine instability detected by a spinal surgeon (validation by flexion/extension films of lumbar spine within the past 6 months showing 4 mm or more translational movement or excessive angular movement manifested by >5 degrees segmental angular movement) e.g. any forms of spondylolisthesis
4. 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
5. Diabetic who is poorly controlled through diet and/or medication (determined by the Investigator)
6. Bleeding diathesis such as coagulopathy or thrombocytopenia
7. Immunocompromised and at an increased risk for infection
8. Systemic infection or local infection that would contraindicate SCS placement
9. Metastatic malignant disease or active local malignant disease
10. 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)
11. Active alcohol, marijuana, recreational or prescription drug abuse or dependence or unwilling to stop/reduce excessive inappropriate medication.
12. 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
13. Life expectancy of less than 1 year
14. Concomitant participation in clinical trial (device or drug)
15. An existing drug pump, SCS system, and/or another active implantable device
16. An interventional procedure and/or surgery within the past 30 days for treatment of pain condition
17. Inability to manage the technical demands of the SCS equipment

Date of first enrolment
19/04/2012

Date of final enrolment
04/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's and St. Thomas' Hospital
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Nevro Corp (USA)

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Sponsor type
Industry

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https://ror.org/02xcxe208

Funder(s)

Funder type
Industry

Funder Name
Nevro Corp (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2017		Yes	No
Results article	results	01/06/2018	02/07/2019	Yes	No