ISRCTN33292457 https://doi.org/10.1186/ISRCTN33292457

Senza™ spinal cord stimulation system for the treatment of chronic back and leg pain in failed back surgery syndrome (FBSS) patients

Submission date 21/03/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 08/04/2011	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/09/2011	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jean-Pierre Van Buyten

Contact details
A.Z. Nikolaas
Moerlandstraat 1
Sint Niklaas
Belgium
9100

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CA2011 PROVA BE

Study information

Scientific Title
Double-Blind, randomised, placebo-controlled clinical trial of the Senza™ spinal cord stimulation system for the treatment of chronic back and leg pain in failed back surgery syndrome (FBSS) patients

Acronym
PROVA

Study objectives
To characterise the effectiveness of the Senza™ System in FBSS patients naive to spinal cord stimulation (SCS)

As of 13/09/2011 the anticipated end date for this trial has been extended from 13/04/2012 to 13/12/2012 and the study design has been updated. The previous study design was as follows: 'Single-centre double-blind two-period prospective randomised placebo controlled crossover study'.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee for Medical Ethics, A.Z. Nicholas (Commissie voor Medische Ethiek, A.Z. Nikolaas) approved on 18th March 2011

Study design
Single-centre double-blind three-period prospective randomised placebo controlled crossover study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Chronic back and leg pain in failed back surgery syndrome (FBSS) patients

Interventions

Subjects who meet screening criteria will receive a permanent SCS implant and randomised to:
1. ON arm for first period/OFF arm for second period or
2. OFF arm for first period/ON arm for second period

Each blinded period will last 2 months with a 2 week washout between periods.

Added 13/09/2011:
3. Immediately following period 2, all subjects will have therapy turned ON for a 6 month open label period

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
1. Visual Analogue Scale (VAS) score for back pain: measured at baseline, the mid-point and end of each period
2. Emergent adverse events

Secondary outcome measures
1. VAS score for leg pain: measured at baseline, the mid-point and end of each period
2. Sleep disturbance: measured at baseline, the mid-point and end of each period
3. Oswestry Disability Index: measured at baseline and the end of each period
4. Subject diary: measured at baseline, prior to mid-point and end of each period, following wash-out
5. Subject's assessment of group assignment: measured at the end of each period
6. Changes in medication usage: measured at baseline, the mid-point and end of each period

Overall study start date
13/04/2011

Completion date
13/12/2012

Eligibility

Key inclusion criteria
1. An adult (at least 18 years of age)
2. Capable of giving informed consent
3. An appropriate candidate for implantation of a spinal cord stimulator
4. Able to comply with the requirements of the study visits and self-assessment questionnaires
5. On stable pain medications for at least 4 weeks prior to the baseline visit
6. A failed back surgery syndrome (FBSS) patient with back pain intensity of at least 5 cm out of 10 cm, with radiating pain that originates from lumbar, L3, L4, L5, and/or S1

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Progressive neurological disease (multiple sclerosis, chronic inflammatory demyelinating polyneuropathy, rapidly progressive arachnoiditis, cauda equina syndrome, and herniated nucleus pulposis causing progressive motor deficit etc.) as manifested by an unstable neurologic condition
2. Has significant pain in other areas that is not intended to be treated with SCS and that could interfere with accurate pain reporting, as determined by the Investigator
3. Significant mechanical instability as determined by the Investigator
4. Pain intensity of always 10 on a 0-10 scale over the past 6 months based on subject recall
5. Metastatic malignant disease or active local malignant disease
6. A life expectancy of less than 1 year
7. A systemic infection or local infection that would contraindicate SCS placement
8. A female of child bearing potential who is pregnant/lactating or not using adequate birth control
9. Evidence of an active disruptive psychological/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
10. Addiction to any of the following: illicit drugs, alcohol (5 or more drinks/day) and/or medication
11. Bleeding diathesis such as coagulopathy or thrombocytopenia
12. Immunocompromised and at risk for infection
13. Diabetic
14. Unresolved issue of secondary gain

Date of first enrolment
13/04/2011

Date of final enrolment
13/12/2012

Locations

Countries of recruitment
Belgium

Study participating centre
A.Z. Nikolaas
Sint Niklaas

Belgium
9100

Sponsor information

Organisation
Nevro Corporation (USA)

Sponsor details
4040 Campbell Avenue
Suite 210
Menlo Park, CA
United States of America
94025

Sponsor type
Industry

Website
http://www.nevro.com

ROR
https://ror.org/02xcxe208

Funder(s)

Funder type
Industry

Funder Name
Nevro Corporation (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