A Prospective, , Post-Marketing Study of the Clinical Outcomes of Wireless Neuromodulation via the Freedom Spinal Cord Stimulation (SCS) System for the Management of Chronic Back and Leg Pain

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system, skull and spine therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON42568

Source
ToetsingOnline

Brief title
Freedom SCS Post-Marketing study

Condition

- Nervous system, skull and spine therapeutic procedures

Synonym
chronic back and leg pain, Failed back surgery syndrome

Research involving

Human

Sponsors and support

Primary sponsor: Clinical affairs
Source(s) of monetary or material Support: Bedrijf Stimwave Technologies

Intervention

Keyword: Freedom, SCS, Wireless

Outcome measures

Primary outcome

Primary outcomes

1. Percentage of pain relief experienced in the area of pain identified at

baseline compared to 12 months post full implant of the Freedom SCS system.

2. Incidence and severity of device related adverse events during the study,

for example:

a. Biological response to the implant procedure requiring treatment (e.g.,

hematoma, dural puncture, skin erosion or infection, allergic reaction)

b. Technical failure of the electrode (e.g., electrode failure, fracture, or

migration/malposition requiring removal/replacement)

c. Technical failure of the external pulse generator (e.g., power level

variations, over/under/intermittent /uncomfortable stimulation, unacceptable

postural effects, device interaction with external stimulus). (Note:

programming changes to increase paresthesia coverage to capture areas of new

pain are not adverse events.)

Secondary outcome

Secondary outcomes

1. To assess compliance data to indicate usability:

o How many hours/day does the patient use the device?

o Is this congruent with the clinician*s advice?

o Is it sufficient to achieve the desired clinical result?

2. To assess the implanters* experience with the Freedom SCS system:

o Technical difficulties or unforeseen problems during implantation

o Implantation duration from skin incision to electrode entry

3. To determine additional beneficial effects such as:

o Patient satisfaction with treatment

o Reduced visits to health care institutes for chronic back and leg pain

o Improved work status

o Improved quality of life function via the ODI and EQ-5D questionnaires at 12 months compared to baseline

o Reduction in use of analgesics

o Reduced operating theater time, skin to skin time, and fluoroscope time

4. To monitor non-device and non-SCS-related adverse events (e.g., new disease states, unrelated death).

Study description

Background summary

Conventional SCS systems have been available for patients for over 20 years. The implant of a conventional SCS systems happens in two fases: "A trial" and "full implant". The leads are externalized during a trial and connected to an external trial stimulator. A "full" or permanent implant" will replace the temporary system If the patient shows the necessary pain relief. The extensions are to be removed and the leads will be connected to an IPG (implantable pulse generator).

The Freedom SCS system works through wireless technology. The electrodes are implanted and engaged by a wireless external battery unit. The electrodes are not externalized and connected to an external trials stimulator. The same electrodes and wireless external unit can be used after the trial if the patient shows the necessary pain relief. There is no need for further surgery in case of a successful trial. The patient will be advised to have the electrodes removed If he/she does not show the necessary pain relief.

Study objective

The purpose of this study is to assess the safety and effectiveness of the Freedom SCS (spinal cord stimulation) System for the treatment of chronic back and leg pain secondary to failed back surgery syndrome (FBSS) over a follow-up period of one year. (See Appendix A in protocol for a description of the Freedom SCS System)

Study design

This is a , prospective cohort post-market study. Subjects will be placed in one of three cohorts based on their reported baseline pain locations. The cohorts include the following:
• Leg Pain Only - Pain localized to unilateral pain of the leg (thigh, knee, calf, or foot).
• Back Pain Only - Pain localized to the low back or buttocks.
• Back pain and leg pain - Pain localized to both the low back and legs (back, buttocks, thigh, knee, calf, or foot).
Investigators will have the option to select one or more stimulators for stimulation at the spinal cord or at the dorsal root ganglion (DRG). Stimulation programs include tonic stimulation, high frequency stimulation or burst stimulation, all of which may be selected via the same implant.

Subjects will return the hospital on 8 different occasions (baseline, implant, trial evaluation, 6 weeks, 3 months, 6 months, 9 months and 12 months). The study will end after a total period of 12 months

Study burden and risks

The implantation of an SCS system involves risks that are similar to other spinal surgical procedures. In addition, implantation or use of a neurostimulation system containing the elements present in the Freedom SCS System includes, but is not limited to, the following risks:
• Allergic or immune system response to implanted material
• Infection
• Bleeding
• Leakage of cerebrospinal fluid
• Inadequate pain relief
• Hematoma that can result in paralysis
• Trauma to the spinal cord
• Uncomfortable and/or extraneous stimulation, including jolting or shocking sensations
• Seroma at the implant site
To protect the subject from these risks, all investigators have previous experience with SCS and will be trained on the Freedom SCS System Instructions for Use and User Manual prior to study commencement.

Contacts

Public
Selecteer

E. Las Olas Blvd Suite 201 901
Fort Lauderdale Fl 33301
US
Scientific
Selecteer

E. Las Olas Blvd Suite 201 901
Fort Lauderdale Fl 33301
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Appropriate Freedom SCS candidate as affirmed by study investigator
• Candidate has a stable spine not suitable for further surgery as confirmed by physician
• 18 years of age or older (no upper age limit)
• Diagnosis of failed back surgery syndrome (FBSS) characterized by chronic, intractable pain of the legs, back, or both legs and back
• At least 6 months since last surgical procedure on the spine
• Average score of 60mm or greater on a VAS scale (Scale of 0 to 100, where 0 equals no pain and 100 equals worst possible pain)
• Pain duration of at least 6 months
• Expected lifespan of at least two years
• Able to comply with study requirements
• Gives informed consent for study participation

Exclusion criteria

• A consistent VAS score of 100 over the past 24 hours as established at Visit 1
• A co-existing condition that could increase the risk of SCS implantation (e.g., severe cardiac or respiratory disorders, coagulation disorder) or planned surgery within the study duration that could be compromised by SCS (e.g., diathermy)
• Pregnant or planning to become pregnant
• Known or suspected substance abuse within the last 2 years
• Major psychiatric disorder (untreated or refractory to treatment) in the investigators opinion
• Cognitive and/or behavioral issues that could impair study participation, (e.g., unreliability; defective memory; noncompliance in taking medications or keeping appointments; or impaired orientation to time, place, and events)
• Documented allergy to Freedom SCS material components
• Co-existing pain condition or participation in another clinical study that could confound the results of this study
• History of another implanted medical device (e.g., explanted spinal cord stimulator, peripheral nerve stimulation, sacral nerve stimulator, pacemaker, or intrathecal drug delivery)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-10-2016
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Spinal Cord Stimulator
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	26-01-2016
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL55060.028.15