The HALO Study: The Pain Supressive Effect of Low Frequency Spinal Cord Stimulation versus High Frequency Spinal Cord Stimulation

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The primary objective of this study is to compare pain suppression in two groups of subjects with chronic unilateral limb pain as a result of FBSS. Low Frequency spinal cord stimulation settings and High Frequency spinal cord stimulation settings...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47008

Source
ToetsingOnline

Brief title
HALO Study (High And Low frequency SCS)

Condition

- Other condition
- Spinal cord and nerve root disorders

Synonym
leg pain, sciatica

Health condition

Chronic pain

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,geen sponsoring

Intervention

Keyword: Chronic leg pain, FBSS, Pain reduction, Paresthesia

Outcome measures

Primary outcome

The primary objective of this study is to compare pain suppression in two groups of subjects with unilateral neuropathic limb pain, due to FBSS. Two parameter settings will be tested i.e. Low Frequency and High Frequency Spinal Cord Stimulation.

Secondary outcome

*Energy use of the battery at different frequencies

*Percentage of subjects with 50% reduction in pain according to the Dutch Neuromodulation Society criteria

*Use of rescue medication in the trial and post-operative period

*Number of amplitude adjustments in trial period

*Discomfort due to stimulation

*Improvement in disability

*Subject satisfaction

*Change in employment status

*Change in sleep pattern

*Monitoring of adverse events to both stimulation types

Study description

Background summary

Rationale: Electrical stimulation of the dorsal columns of the spinal cord (Spinal Cord Stimulation or SCS) for pain relief has been used in humans for several decades. The most common indication for SCS is the treatment of refractory neuropathic leg pain, particularly when these symptoms persist after an anatomically successful operation (Failed Back Surgery Syndrome or FBSS).

Low frequency * conventional - SCS (LF-SCS) is applied in frequencies ranging from 30Hz to 100 Hz and the subject feels paraesthesias in the painful area, which is considered the ideal situation. Recently, LF-SCS has been challenged by the development of stimulation modes at higher frequencies which provide pain relief at sub-perception threshold, i.e. without paraesthesias. A recent case series reported that High Frequency Spinal Cord Stimulation (HF-SCS) with frequencies ranging fromo 500- 10 000Hz, appears to show better pain relief for both back and limb pain in comparison to LF-SCS, and also to be effective in some subjects who did not respond to LF-SCS.

We propose a study to compare the pain supression of Low Frequency SCS (LF-SCS) with High Frequency SCS (HF-SCS) in an double blind, randomized, controlled, crossover study.

Study objective

The primary objective of this study is to compare pain suppression in two groups of subjects with chronic unilateral limb pain as a result of FBSS. Low Frequency spinal cord stimulation settings and High Frequency spinal cord stimulation settings will be compared to the baseline pain scores (Visual Analogue Scale).

Study design

A prospective, double blind, multi-centre, randomized, crossover study of SCS in the treatment of subjects with refractory neuropathic leg pain after back surgery. 30 subjects will be included and divided over 5 centres. Subjects will be randomized on a 1:1 basis to either the LF or the HF group, and will cross to the other group after a wash-out period.

Intervention

All subjects will be stimulated with both standard forms of spinal cord stimulation: Low Frequency (LF-SCS) at 30Hz and High Frequency (HF-SCS) at 1000Hz, with the same SCS device, for 9 (+3) days and then enter a five day wash-out period before transferring to the other arm of the study. The order in which they receive the therapy will be determined by the blinded randomization procedure.
At the end of the trial period, positive responders will be implanted with an internal pulse generator (IPG), according to their preference of stimulation and will be followed-up for 1 year according to standard care, as outlined by the Dutch Neuromodulation Society, on which this protocol is based.
Non-responders, (expected to be up to 10% of subjects), will have the hardware removed and will not be followed up regarding the secondary endpoints.

Study burden and risks

Both methods of stimulation are standard clinical practice performed routinely in the study centres; there is therefore no extra risk to the subjects. The protocol is based on the standard care and post-operative follow-up of SCS subjects as proposed by the Dutch Neuromodulation Society. Both groups will receive this standard care. The only difference is change of stimulation frequency. There is therefore no extra physical risk to the patient.
The duration of the trial-period falls within the generally accepted period of 30 days for trial stimulation. This trial will end after 23 (+6) days including both trial phases and the wash-out period. During the trial period, subjects may use escape medication. There is therefore no extra burden to the subject.
Possible benefit to the subject is that both forms of stimulation will be evaluated. This may lead to a better quality of life in the HF-SCS Group as result of pain relief without paraesthesias. Furthermore, non-responders to LF-SCS may benefit from HF-SCS. Standard follow-up care and protocolled post-operative procedures will be followed in both study groups

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

*Subjects are male/ female, 18 years to 70 years
*Chronic, persistent, refractory, unilateral neuropathic limb pain, as a result of spinal surgery
*Failed conservative treatments for chronic pain including but not limited to pharmacological therapy, physical therapy and minimally interventional pain procedures for chronic pain
*Pain radiating in the leg, following segments L4 and/or L5 and/or S1 for at least 6 months
*Minimum baseline pain intensity as assessed by VAS of * 50mm on 100mm scale in the primary pain area
*Subject is able and willing to provide informed consent
*Subject is able and willing to comply with the protocol and follow-up schedule
*Subject has been included for implantation according to standard criteria from the Dutch Neuromodulation Society

Exclusion criteria

*Back pain component of more than 20% or VAS > 40mm on 100mm scale
*Bilateral limb pain
*Subjects with a previous SCS implantation.
*Changes in pain medication in the 2 months preceding the trial period;
*Expected inability of subjects to correctly operate the neurostimulation system
*Presence of any other clinically significant or disabling chronic pain condition e.g. hip arthrosis, rheumatoid arthritis, fibromyalgia, etc.
*History of coagulation disorders, lupus erythematosus, diabetes mellitus, or morbus Bechterew

*Symptoms or proof of any malignant disease
*Current use of medicines affecting coagulation which cannot be temporarily stopped
*Evidence of an active disruptive psychiatric disorder or other known condition significant enough to impact the perception of pain, compliance to intervention and/or ability to evaluate treatment outcome as determined by the investigator
*Life expectancy of less than 1 year
*Existing or planned pregnancy in the trial period
*BMI <20 and > 35 * a maximum and minimum BMI limit are imposed due to the technical difficulties and risk of complications in underweight or morbidly obese subjects.
*Participation in another clinical study in the last 30 days

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2014
Enrollment:	30
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	20-12-2013

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-12-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT02112474
CCMO	NL43067.018.13