Spinal versus local anaesthesia for CL-SCS implantation and its influence on the ECAP

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20564

Source
NTR

Brief title
Spilocap

Health condition

Failed back surgery syndrome

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

• To evaluate patient pain and comfort level under spinal or local anaesthesia during SCS trial lead implantation.

Secondary outcome

• To evaluate the difference in amount of propofol anaesthesia and additional pain medication required by patients when implanting SCS leads, during SCS trial lead implantation under spinal or local anaesthesia.
• To evaluate the degree of pain relief achieved during the SCS trial period.
• To evaluate patient and physician satisfaction with the trial lead implantation procedure.
• To evaluate the effect of spinal or local anaesthesia on ECAPs elicited by SCS during SCS lead implantation.
• To evaluate the effect of spinal, local and general anaesthesia on nerve conduction velocity.
• To evaluate differences in sensitivity to stimulation during and post-washout of spinal or local anaesthesia.
• To evaluate differences in ECAP recordings from different postures.

Study description

Background summary

Spinal Cord Stimulation (SCS) has been used successfully to treat FBSS patients for fifty years now. Usually the SCS is implanted under local anaesthesia with or without sedation (propofol), In the Elisabeth Tweesteden Hospital (ETZ) Tilburg the procedure is usually performed successfully under spinal anaesthesia for a few years now. Up until today there is no published data on the utility of using spinal anaesthesia during SCS procedures.

Closed-loop spinal cord stimulation (CL-SCS) is a new form of SCS which differs from other SCS systems as, in addition to standard SCS treatment, it is capable of measuring evoked compound action potentials (ECAPs) and automatically adjusting therapy output in response to electrophysiological signals from the patient’s spinal cord. CL-SCS has CE approval and is used in the Netherlands for more than 1 year.

In this double arm open label study, subject experiences during SCS lead implantation using either spinal anaesthesia or local anaesthesia will be evaluated. We will also review differences in subject and physician satisfaction and capture any observed effects of the different anaesthesia regimes on ECAP generation and propagation.
Propofol sedation will be given if requested by the patient in whatever method of anaesthesia is chosen.
All procedures will be performed in the Elisabeth Tweesteden Hospital (ETZ) in Tilburg.

Study objective

Spinal anesthesia is a superior anesthesia technique for spinal cord stimulation procedures

Study design

-Main study parameters for primary objective:

• Subject experience will be evaluated using a numerical pain rating scale (NPRS) to assess the degree of pain/discomfort during the lead implantation procedure. A clinically meaningful difference in NPRS is set at two points on the NPRS scale (0-10)

Secondary study parameters/endpoints for secondary objectives:

• To evaluate the difference in amount of propofol sedation required. Dosages administered will be captured during procedure.
• Physician and patient satisfaction will be evaluated using a 5-point Likert scale.
• The effects of spinal and local anaesthesia on ECAP generation will be assessed in the following ways. These evaluations will take place intra-operatively, post-operatively in the recovery room (<1 hr post-procedure) and on the morning following the lead or IPG implantation procedure:
o As to whether or not ECAPs can be generated a simple Yes/No question will be answered.
o An activation profile will be created to describe the relationship between device output and spinal cord activation – the values for this activation profile and subject sensitivity will be captured.
o Conduction velocity (CV) evaluations will be performed using software on the CL-SCS system.
• Effects of posture on ECAP recordings will be assessed by repeating the activation profile exercise in the supine, sitting and standing positions. This will only be conducted after anaesthesia has fully washed out (only performed one day after implantation).
• Pain relief will be assessed by comparing baseline pain intensity to that reported at the end of the SCS trial period using a numeric pain rating scale (NPRS).
• The effect of general anaesthesia on ECAP will be evaluated by performing a CV evaluation intra-operatively during permanent IPG implantation and post-operatively when subjects are fully awake using software on the CL-SCS system.

Intervention

spinal or local anesthesia with or without sedation

Contacts

Public
Elisabeth Tweestedenziekenhuis
Johan van de Minkelis

0132216881
Scientific
Elisabeth Tweestedenziekenhuis
Johan van de Minkelis

Eligibility criteria

Inclusion criteria

• Subject has been diagnosed with chronic, intractable leg and/or back pain (NPRS ≥ 6), which has been refractory to conservative therapy for at least 6 months;
• Subject has been approved by the Investigator to undergo a trial of spinal cord stimulation;
• Subject is an appropriate candidate for the surgical procedures required for SCS based on the clinical judgment of the implanting physician;
• Subject is on a stable dose (no new, discontinued, or changes in dose) of all prescribed pain medication for at least 30 days prior to baseline evaluation;
• Subject is willing and capable of giving written informed consent;
• Subject is willing and able to comply with study-related requirements, procedures, and visits.

Exclusion criteria

• Subject has a medical condition or pain in area(s) that could interfere with study procedures, accurate pain reporting, and/or confound evaluation of study endpoints, as determined by the Investigator;
• Subject is not an SCS candidate due to anatomical or structural findings and/or changes which would benefit from surgical intervention as determined by investigator;
• Subject has evidence of an active disruptive psychological or psychiatric disorder or other known condition significant enough to impact perception of pain, compliance with intervention and/or ability to evaluate treatment outcomes as determined by the Investigator;
• Subject has had another neuromodulation system;
• Subject has a condition currently requiring or likely to require the use of MRI or diathermy;
• Subject is not a good surgical candidate (e.g., has an uncontrolled coagulation disorder, bleeding diathesis, progressive peripheral vascular disease, uncontrolled diabetes mellitus, or cannot come off anticoagulant therapy for procedure);
• Subject is concomitantly participating in another clinical study unless pre-approved by the Principal Investigator;
• Subject is involved in a process (e.g., involved in an injury claim under current litigation) in which pain relief may be considered detrimental (i.e., secondary gains).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2021
Enrollment:	24
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	30-03-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54096
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9392
CCMO	NL75858.028.20
OMON	NL-OMON54096

Study results