A prospective, randomised, double-arm, open label exploratory trial to investigate patient and physician experiences of spinal or local anaesthesia and its influence on ECAPs during SCS trial lead implantation.

Published: 03-03-2021
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• To evaluate patient pain and comfort level under spinal or local anaesthesia during SCS trial lead implantation.

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

Summary

ID

NL-OMON54096

Source
ToetsingOnline

Brief title
SPILOCAP study

Condition

- Other condition

Synonym
chronic nerve pain, failed back surgery syndrome

Health condition

Chronic pain as a result of FBSS

Research involving
Human

Sponsors and support

Primary sponsor: Elisabeth-Tweesteden ziekenhuis
Source(s) of monetary or material Support: ETZ tilburg

Intervention

Keyword: ECAP, Local Anaesthesia, Patient and physician experience, Spinal Anaesthesia

Outcome measures

Primary outcome

• 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 outcome

• To evaluate the difference in amount of medication for sedation required, including additional pain medication. 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.

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.

Study objective

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

Study design

Prospective randomised, double-arm, open label exploratory trial designed to investigate patient experiences of spinal or local anaesthesia during SCS trial lead implantation.

Intervention

one group will recieve spinal anesthesia during implantation of de electrodes, the other group recieves local anaesthesia with sedation.

Study burden and risks

Burden and risks

There are only minor additional risks to participation in this study. The implantation of the system is a standard procedure in the hospital and the data that is collected consists of questionnaires regarding satisfaction, pain intensity and pain relief, subject satisfaction, and stimulation induced sensation.
Data collection activities will add approximately 10 to 30 min to the normal length of time required depending on the number of tests conducted during the visit.

Benefit and group relatedness

There will be no immediate benefit to study participants. However, the results of this study may add to the knowledge on the use of spinal or local anaesthesia and subjects experience with these alternative methods. This information will hopefully inform future trial design and lead to improved treatment for patients undergoing SCS lead implantation. While the sample size for this pilot study is not powered we believe that a sufficient sample size has been identified to enable the design of a future randomized controlled trial (RCT) to confirm or contest preliminary findings from this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Subject has been diagnosed with chronic, intractable leg and/or back pain (NPRS >= 6), FBSS, which has been refractory to conservative therapy for at least 6 months.
• Subject has been approved by the Investigator to undergo a trial of SCS implantation.
• 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.
• Subject is at least 18 years of age

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-04-2021
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	03-03-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-02-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	10-05-2023
Application type:	Amendment
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

ID: 20564
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL75858.028.20
OMON	NL-OMON20564