ECAP Guided SCS Lead Implantation: an interventional feasibility study

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

Summary

ID

NL-OMON49096

Source
ToetsingOnline

Brief title
ECAP Guided SCS Study

Condition

- Other condition
- Spinal cord and nerve root disorders

Synonym
Failed Back Surgery Syndrome; Chronic pain in trunk and/or limbs

Health condition

Treatment for chronic pain

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Most of the procedures are standard care. There is no additional funding for this study.

Intervention

Keyword: ECAP, FBSS, SCS

Outcome measures

Primary outcome

The primary study parameter, successful ECAP guided lead placement, will be determined at the end of phase 1, 2 (if applicable) and 3 (if applicable). The study will be considered a success if phase 3 is completed and passes the test for phase three.

Secondary outcome

The following parameters will be measured as secondary study parameters:

1. Neurophysiological characterisations

Recorded ECAP signals will be analysed after the procedure in the OR to describe their morphology and propagation characteristics - these parameters describe the type and physiology of the nerves activated by the epidural leads and nerve root stimulus

2. Patient reported outcomes (collected at baseline, 3-, 6- and 12-months follow-up). These will be collected via an online set of questionnaires including:

• Health related quality of life (EQ-5D-5L)

• Brief Pain Inventory (BPI)

• Pain Detect

• Oswestry Disability Index (ODI)

• Hospital Anxiety and Depression Scale 2.1 (HADS)

• Patient Global Impression of Change (PGIC)

3,4,5 and 7: Device data concerning programming parameters after initial programming and at follow-ups (contacts used, pulse width, stimulation frequency and amplitude etc.) will be collected to assess: if the best candidate electrodes identified in the operating room are used post operatively (3). This same device data will be used to assess; if and how initial programs change over time (4), to describe the programming parameters used (5), if ECAPs can still be recorded at long-term follow up visits, and if there are any detectable neurophysiological changes over time (7).

6. Procedural times will be captured on paper/electronic forms and programming time will be derived from the device data captured on the Clinical Interface

Study description

Background summary

The positioning of Spinal Cord Stimulation (SCS) leads in the epidural space to deliver therapy for chronic pain currently relies on intra-operative feedback from the patient during the procedure. This feedback is not always very reliable due to sedation, discomfort and peculiar positioning (prone) of the patient on the operating table. By utilising the recording capabilities of a new type of SCS system it may be possible to use objective neurophysiological signals to optimally place leads. This could potentially improve the speed and accuracy of the operation to implant the epidural leads and make the procedure more comfortable for the patient.

Study objective

The primary objective of this study is to assess the feasibility of placing neurostimulator leads in the epidural space based on intraoperatively recorded ECAPS

Study design

This is a single-centre, open label, interventional, prospective feasibility study with three distinct phases including an interim analysis of results following each phase

Intervention

During the operative procedure standard Radio Frequency (RF) needles will be used to transiently stimulate the nerve roots believed to carry sensory nerve fibres that innervate the patients painful area. This will be done as well as (phase 1 and 2) or instead of (phase 3) normal stimulation sensation mapping through the epidurally implanted SCS leads.

Study burden and risks

Burden: The operative procedure may be a little longer than usual (20 minutes) which may lead to increased discomfort for the patient.
Potential risks: There is an increased risk (in phase 3) of a second operative procedure to reposition the lead if the ECAP based placements appears to be sub-optimal. This may lead to an extended trial period with a slight increase in the risk of infection.
There are no other expected risks aside of the known risks for neuromodulation treatment.

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

1. Subject has been included for implantation according to standard criteria from the Dutch Neuromodulation Society
2. Chronic refractory pain as a result of post-laminectomy syndrome (FBSS) for at least 6 months
3. Subject is 18 years or older
4. Subject is able and willing to comply with the protocol and follow-up
5. Subject is fluent in the Dutch language
6. Subject is able to provide written informed consent

Exclusion criteria

1. Subject is under 18 years old
2. Subject is pregnant or nursing
3. Subject is unable to operate the EvokeTM SCS System
4. Subject is an unsuitable candidate for SCS

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-04-2022
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	EvokeTM Closed Loop Spinal Cord Stimulation System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-05-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
Other	Na EC goedkeuring wordt het onderzoek in het Nederlands trial register geregistreerd, voordat de eerste patient wordt geincludeerd.
CCMO	NL69419.100.19