Quantifying various effects of closed-loop Spinal Cord Stimulation (SCS) on pathophysiological mechanisms in Complex Regional Pain Syndrome (CRPS); an explorative study

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To evaluate and quantify the various clinical effects of closed-loop SCS versus open-loop SCS on the underlying pathophysiological effects in CRPS.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON49652

Source
ToetsingOnline

Brief title
Closed-loop SCS for CRPS

Condition

- Peripheral neuropathies

Synonym
complex regional pain syndrome, reflex sympathetic dystrophy

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: closed-loop, complex regional pain syndrome (CRPS), pathophysiological mechanisms, spinal cord stimulation (SCS)

Outcome measures

Primary outcome

The primary study parameter is the change in pain intensity at the end of the

study compared with baseline.

Secondary outcome

Changes between the end of the study and baseline on all other parameters will

be assessed and reported as secondary endpoints for this study.

Study description

Background summary

Conventional open-loop neurostimulation can offer relief for several intractable pain conditions including complex regional pain syndrome (CRPS). Spinal Cord Stimulation (SCS) is a thoroughly tested and well-described neurostimulation technology.
Recently developed innovative closed-loop SCS controls stimulation dose by measuring the recruitment of fibres in the dorsal column and by using the amplitude of the evoked compound action potentials (ECAPs) to maintain stimulation within an individualized therapeutic range.
CRPS is a complication after surgery or trauma. One or combinations of several pathophysiological mechanisms can play a role: inflammation, sensory processing disturbances, vasomotor, sudomotor and motor disturbances. This results in different phenotypes of CRPS. The effect of conventional open-loop SCS in CRPS can be related to a direct influence of SCS on at least a subset of its underlying pathophysiological mechanisms. The additional benefits of closed-loop SCS on the various pathophysiological mechanisms in CRPS are still

to be studied

Study objective

To evaluate and quantify the various clinical effects of closed-loop SCS versus open-loop SCS on the underlying pathophysiological effects in CRPS.

Study design

Single-centre, explorative, prospective, open-label, single-blind, internally controlled study.

Intervention

Patients will receive standard care and will have all the standard follow-up visits and two additional visits. At every visit standard data is collected. However, at baseline and each follow-up visit patients will get one or more additional measurements to acquire quantitative data on various clinical effects that the SCS can have on the underlying mechanisms of CRPS.
In addition, there will be a one-month period in the follow-up period during which the stimulation will be switched to open-loop and a one-month period with closed-loop for every participant, to allow for an internal control of the stimulation effects.

Study burden and risks

Burden - Patients participating in the study will be subjected to some additional burden, namely:
Two additional hospital visits will be required as compared to standard of care treatment.
Patients will need to spend approximately 1hr longer than normal at the hospital to complete baseline assessments, 45min longer than normal to complete assessments at follow up visits prior to the 3-month visit and 1hr longer than normal to complete assessments during 3-6-months follow up.
Risks - Additional risks to patients are minimal. Additional risks are associated with the blood test and travel to/from the hospital for additional visits
Benefit - There may be no direct benefit to patients participating in the protocol but knowledge gained may benefit similar patients in the future.
Group relatedness - SCS is an established treatment option for refractory pain associated with CRPS, we anticipate that this study will act as further confirmation for this. We also foresee that the secondary investigations on effect of SCS on particular CRPS phenotypes will better inform decision making on the use of SCS in these particular presentations.

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

a subject must meet the standard Dutch Neuromodulation Society consensus criteria for spinal cord stimulation and the following study criteria:,
- Over 18 year old
- Diagnosed with retractable unilateral, upper- or lower limp CRPS,
- Capable and willing to participate in the additional measurements.

Exclusion criteria

- Pain of other aetiology in addition to CRPS,
- Previously failed neuromodulation treatment (SCS or DRG).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-12-2020
Enrollment:	20
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	18-08-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-11-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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 goedkeuring door de METC wordt de studiein een trial register aangemeld
CCMO	NL74145.078.20