Motor Response after Dorsal Root Ganglion Stimulation: A pilot study of 10 patients with Motor Complete Paraplegia.

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The aim of this case series is to investigate if DRG stimulation can evoke motor responses in the lower extremities in patients with motor complete spinal cord injury. This will be measured using EMG.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON47916

Source
ToetsingOnline

Brief title
DRG Motor Response Study

Condition

- Spinal cord and nerve root disorders

Synonym
Paraplegia, Spinal Cord Injury

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: Dorsal Root Ganglion, Electrical Stimulation, Motor Response, Paraplegia

Outcome measures

Primary outcome

The aim of this case series is to investigate if DRG stimulation can evoke

motor responses in the lower extremities in patients with motor complete spinal

cord injury.

Secondary outcome

In addition to motor response, we will try to investigate the following

secondary objectives:

- Weight-bearing ability (Non-assisted standing)

- Assisted Standing

- Muscle Strength (measured using a MicroFet 2 dynamometer and the MRC scale

for muscle strength)

- Voluntary movements

- Patient Expectations of experimental treatment

- Pain experience during stimulation

Study description

Background summary

Spinal Cord Stimulation (SCS) en Dorsal Root Ganglion (DRG) stimulation are considered to be accepted treatment modalities for the indication of pain. In 2014, the research group of Angeli et al. proved that spinal cord stimulation can evoke motor response and even voluntary movements in patients with motor

complete paraplegia. However, spinal cord stimulation has many disadvantages, which prevents a broad, clinical implementation of the DRG stimulator for motor response in patients with paraplegia. We propose the more direct form of DRG stimulation as a fruitful alternative.

In a previous, still-ongoing pilotstudy we have so far been able to evoke motor response in 6 patients implanted with a DRG stimulator for the indication of pain management. From this we have been able to conclude that DRG stimulation indeed can lead to a motor response in these intact patients. The study is still ongoing in order to reach the target of 10 included patients, before finishing up the study and publishing the results.

As indicated in the protocol of the pilotstudy with these intact patients, we would like to perform a follow-up study investigating the possibility to evoke motor responses in patient with spinal cord injury, using DRG stimulation.

Study objective

The aim of this case series is to investigate if DRG stimulation can evoke motor responses in the lower extremities in patients with motor complete spinal cord injury. This will be measured using EMG.

Study design

Prospective case series

Intervention

All ten patients in this pilot study will receive a surgical placement of a DRG stimulator. In addition, they will undergo EMG measurements and other tests (see section on primary and secondary outcomes) to objectify the possible effect of DRG stimulation on motor response. The controls consist of the intact patients used in the previous pilot (MEC-2015-575).

Study burden and risks

The only risks the patient would be exposed to are the risks that come with the temporary surgical placement of the DRG stimulation device. This treatment has been performed many times in the Center for Pain Medicine of the Erasmus MC with low complication rates. Although we will subject the patients to a surgical placement of the DRG stimulator before EMG measurement, the treatment itself will be performed under local anesthesia. In addition, risks such as epidural hemorrhage, infection, spinal cord compression, cerebrospinal fluid (CSF) leakage, paralysis, weakness, numbness, or pain below the level of the implant, are considered to be very low when performing the procedure in patients for the indication of pain. Especially given the fact that our

patients will have the stimulator in situ for only three days (instead of the usual two week proof period of DRG stimulator placement), we expect the risks to again be minimized.
We also consider the radiation exposure during the surgical placement of the stimulator in the OR (1.6 mSv) to be acceptable, especially in comparison to the background radiation found in the Netherlands (2.0-2.5 mSv).

We also conclude that the burden of EMG measurements and physical examination can be considered to be minimal.

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

- Paraplegia caused by trauma >2 years prior to inclusion

- Grade A or B neurological deficit on the ASIA Impairment scale
- Age >17 years
- Any Wounds (e.g. decubitus)

Exclusion criteria

- Depression or an anxiety disorder
- Pregnancy
- Life expectancy < 1 year

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-06-2018
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	St. Jude Medical Spinal Modulation Dorsal Root Ganglion Stimulator
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	30-11-2017

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-09-2018
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
CCMO	NL60957.078.17