Dorsal root ganglion stimulation and motor responses in patients, who have been implanted with a dorsal root ganglion stimulation device: a pilot study

Published: 20-10-2015
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The aim of this pilot study is to investigate if DRG stimulation can evoke motor reactions in the lower extremities in patients who have already been implanted with a DRG stimulator to treat neuropathic pain.

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

Summary

ID

NL-OMON43596

Source
ToetsingOnline

Brief title
DRG study

Condition

- Spinal cord and nerve root disorders

Synonym
Motor reponse

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 stimulation, Motor responses, Pilot study

Outcome measures

Primary outcome

The main study parameter is to evoke motor reactions in the lower extremities

in patients who have already been implanted with a DRG stimulator to treat

neuropathic pain.

Secondary outcome

Not applicable.

Study description

Background summary

Spinal Cord Stimulation (SCS) and Dorsal Root Ganglion (DRG) stimulation are well established treatment modalities to manage pain control. In 2014 Angeli et al demonstrated that neuromodulation can also be used to facilitate standing and stepping in patients with a complete motor Spinal Cord Injury (SCI). We want to investigate if a DRG stimulator can evoke motor reactions in the lower extremities in patients who have already been implanted with a DRG stimulator to treat neuropathic pain. If we can evoke motor reactions in the lower extremities in these patients, we will start a follow up study.

Study objective

The aim of this pilot study is to investigate if DRG stimulation can evoke motor reactions in the lower extremities in patients who have already been implanted with a DRG stimulator to treat neuropathic pain.

Study design

This is a prospective pilot study

Study burden and risks

The burden associated with participation is that they will have to undergo the following test: EMG. This test doesn't hurt. There aren't risks associated with participation.

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

Patients who are surgically implanted with a lumbar DRG stimulation device.

Exclusion criteria

Depression or an anxiety disorder
Pregnancy
Life expectancy < 1year

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-06-2016
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	20-10-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-05-2016
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	NL54623.078.15