Understanding the influence of pain and spinal cord stimulation on evoked potentials and EEG

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

Summary

ID

NL-OMON37470

Source
ToetsingOnline

Brief title
Pain, SCS, EPs and EEG

Condition

- Spinal cord and nerve root disorders

Synonym
chronic neuropathic pain, chronic pain as a result from injury to the nervous system

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chronic pain, EEG, Evoked Potentials, Spinal cord stimulation (SCS)

Outcome measures

Primary outcome

The amplitudes of the reconstructed signal of the primary somatosensory cortex (S1) evoked by stimulation of Aβ-fibers and Aδ-fibers and pain scores, determined by a visual analog score (VAS). These amplitudes and pain scores will be compared in the tonic SCS, burst SCS, SCS off and controls.

Secondary outcome

Secondairy study parameters are the activity of other brain areas after Aβ and Aδ stimulation. In the rest EEG this activity is measured as power per frequency band. Other study parameters are the presence of allodynia, experience of paresthesias, pain scores per body part and quality of the pain (sharp, burning, etc.)

Study description

Background summary

In patients with severe chronic (neuropathic) pain, spinal cord stimulation (SCS) is an option. However, even after careful selection of patients, not in all patients pain is relieved by at least 50%. The cause of this is unknown. However, recently a new stimulation method is developed (burst, a software setting) of which it is claimed that is relieves pain better than conventional (tonic) SCS and it would elicit no or less paresthesias. The working mechanism and effects of tonic SCS are partly known, but burst stimulation is not studied yet. By studying patients in tonic, burst and no SCS and controls without pain, knowledge of the effects of SCS and pain on the brain can be obtained. Measurements in tonic and burst stimulation have already been performed in 19 patients and about 21 patients will follow.

Study objective

The primary objective is to find out whether there is enhanced processing of sensory stimuli when people are in pain and to find out whether SCS has influence on the processing of sensory stimuli applied on non painful body parts. We focus on the activity of the primary somatosensory cortex (S1). Secondary objectives are to assess how SCS and pain modulate the activity of other brain areas and to identify a possible pain network. We will also assess this in the measurements of the rest EEG. The influence of the presence of paresthesias, allodynia and kind of pain on EPs and the EEG will be assessed. The last objectives are to put the pain scores during the trials of burst stimulation in the perspective of the pain scores that patients have in the case they have no stimulation and to assess the prognostic value of evoked potentials (EPs) and EEG for the success of (burst) stimulation.

Study design

The study is a prospective pilot study in which all patients that had a period of burst stimulation and in whom already measurements are performed are included. Therefore we will have repeated measurements of the patients. As controls, subjects without pain are included.

Intervention

The patients are asked to turn off their stimulator 12 hours before the measurements and keep the stimulator turned off until the measurements are performed. For the control group there is no intervention.

Study burden and risks

Participating patients are asked to turn off their stimulator which probably will increase their pain. However, patients are obliged to turn of the SCS when they drive and most patients turn off the stimulator each night. When measurements are in the morning the extra time they have turned off the stimulator is small. The appointment will be coupled to a regular checkup. For the controls there is no intervention, however they must travel to the Clinical Neurophysiology department of the MST hospital. There, patients and controls will undergo the EEG and EP measurements with a duration of about 20 minutes. The measurements of the EEG and EPs are very well tolerable. Including positioning of the EEG cap and preparation, the individual study duration will be 1.5 hour. There is no individual benefit for the subjects participating in the study. There are no health risks associated with the study, nor are there any harmful aspects with respect to participating.

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: patients who participated in a trial for a new form of stimulation (burst stimulation) and in whom EP and EEG measurements are performed during the case they still had classing (tonic) stimulation and during the case they had two week burst stimulation.
Controls: aged matched volunteers

Exclusion criteria

Patients: hospitalisation or other form of serious decline of general health
Controls: Chronic pain, former brain surgery, diagnosed neurological disease

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-03-2012
Enrollment:	0
Type:	Actual

Ethics review

Approved WMO Date:	06-03-2012
Application type:	First submission
Review commission:	METC Twente (Enschede)

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: 20960

Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL39441.044.12
OMON	NL-OMON20960