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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20960

Source
Nationaal Trial Register

Health condition

Chronic neuropathic pain - Chronische neuropatische pijn
Spinal cord stimulation - Ruggermerg stimulatie
EEG
Evoked potentials (EP)

Sponsors and support

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Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

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

Rationale:

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.

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 measurements of EEG in rest. The influence of the presence of paresthesias, allodynia and kind of pain on evoked potentials (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 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.

Study population:

The patients that will be included are the same patients that already underwent burst stimulation and EP and EEG measurements, which are 40 patients. They are all adults. The control group consists of 20 volunteers without chronic pain. This group will be aged-matched to the patients.

Intervention:

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

Main study parameters/endpoints:

The main study parameters are the amplitudes of the reconstructed signal of the 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 tonic SCS, burst SCS, SCS off and controls.

Study objective

In chronic pain the processing of sensational and painful stimuli will be disturbed. In patients with effective spinal cord stimulation the processing will normalize.

Study design

N/A

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.

Contacts

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Eligibility criteria

Inclusion criteria

A patient group and a control group will be included.

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:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2012
Enrollment:	60
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 37470
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3154
NTR-old	NTR3298
CCMO	NL39441.044.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37470

Study results

Summary results
N/A