Burst SCS evaluated

No registrations found.

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

Summary

ID

NL-OMON23297

Source
NTR

Brief title
SCS: Bursts

Health condition

neuropathic pain

Sponsors and support

Primary sponsor: Medisch Spectrum Twente, Enschede
Source(s) of monetary or material Support: Medisch Spectrum Twente, Enschede

Intervention

Outcome measures

Primary outcome

The main study parameters are the scores on the VAS for pain.

Secondary outcome

Secondary parameters are the scores on VAS for quality of life, the McGill Pain Questionnaire, the Patients' Global
Impression of Change (PGIC) scale, and the estimated walking distance. These scores will be

compared for the
conventional tonic, burst and sham stimulation situations. In a subgroup of patients with failed back surgery syndrome we will study the differences in brain activation between the stimulation settings, measured by changes in EEG features and
evoked potentials.

Study description

Study objective

The present mode of (tonic) SCS is accompanied by paraesthesia in the area of stimulation. Recently, a new mode of
SCS has been developed which makes it possible to apply spinal cord stimulation without paraesthesias. This mode is
called burst stimulation, in which is periods of stimulation are interspersed with periods without stimulation. Burst SCS,
makes it not only possible to stimulate without paresthesias, but could possibly also be more effective in the treatment of
neuropathic pain. In this study we want to evaluate which mode of SCS (burst stimulation, or conventional tonic
stimulation) is the most effective for the treatment of neuropathic pain.

Study design

During the 6 weeks study period, the patients will visit the hospital every two weeks. During those visits the primary and secondary will be evaluated.

Intervention

Patients will receive two different SCS stimulator settings (burst and sham) each for a two week period.

Contacts

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Eligibility criteria

Inclusion criteria

Over 18 years,
SCS for at least 3 months,
Optimal tonic stimulation,
SCS system type Eon, EonC, Eon mini or Prodigy (SJM, Plano, TX),
Capable of participation: travelling to the hospital and filling out the questionnaires.

Exclusion criteria

Hospitalisation or other form of serious decline of general health,
Severe pain that is interfering with the pain the SCS is used for,
Received burst SCS in the past,
Incapable of working with rechargeable system in the future.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2014

Enrollment:	58
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL4339
NTR-old	NTR4479
CCMO	NL48576.044.14

Study results