Percutaneous nerve stimulation in severe neuropathic pain patients due to spinal cord injury: a feasibility study

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To evaluate the feasibility of PENS in patients with chronic neuropathic pain due to SCI.

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

Summary

ID

NL-OMON34598

Source
ToetsingOnline

Brief title
Percutaneous nerve stimulation in neuropathic pain due to SCI

Condition

- Spinal cord and nerve root disorders

Synonym
neuropathic pain, pain

Research involving
Human

Sponsors and support

Primary sponsor: Reade, voormalig revalidatiecentrum amsterdam RCA
Source(s) of monetary or material Support: subsidieaanvraag loopt bij ZON-mw

Intervention

Keyword: neuropathic pain, neurostimulation, spinal cord injury

Outcome measures

Primary outcome

The feasibility will be evaluated with structured evaluation forms assessing performance of the intervention according to the protocol, attendance of the patients, experiences of patients, adverse events, and completion of the questionnaires. Other aspects are the recruitment process, and the percentage of responders.

Secondary outcome

The secondary outcome parameters include International Spinal Cord Injury Basic Pain Data Set self report measures; pain intensity (0-10 on a numerical rating scale); Neuropathic Pain Symptom Inventory; Hospital Anxiety and Depression Scale; Short Form-36 walk-wheel (SF36-ww); and Patients' Global Impression of Change scale.

Study description

Background summary

One of the most severe and common complications of a spinal cord injury (SCI) is neuropathic pain. Medication is usually not sufficient to treat effectively neuropathic pain, and it can cause side effects. Acupuncture has been suggested as a treatment modality for neuropathic pain. Only a few studies have been done to evaluate the effectiveness of acupuncture in patients with chronic pain due to SCI . The methodological quality of current studies is poor. We are planning a high quality randomized clinical trial on the effectiveness of percutaneous electrical neurostimulation (PENS), derived from acupuncture, in patients with chronic pain due to SCI. We will first conduct a feasibility study.

Study objective

To evaluate the feasibility of PENS in patients with chronic neuropathic pain due to SCI.

Study design

A feasibility study with one group pre-test/post-test design. Patients will be given 12 sessions of PENS within 18 weeks. Feasibility will be evaluated after 8 weeks (T8),18 weeks (T18) and 12 weeks after the last treatment (T30). Outcome parameters will be measured at T0, T8, T18 and T30. In total 15 patients will be included.

Intervention

Percutaneous neurostimulation, eventually with additional electrical current on the needles, will be given according to a semi standardized protocol.

Study burden and risks

Because of the intractable pain a substantial part of the spinal cord injury patients experience, the benefit of PENS could be considerable. PENS is very safe in the hands of experienced and qualified practitioners. The only side-effects that could occur are minor like slight haemorrhage, haematoma and dizziness

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

• 18 to 70 years of age,
• SCI at any level and any American Spinal Cord Association (ASIA) impairment Score
• SCI occurred at least 6 months before inclusion
• Diagnosis neuropathic pain on the DN4 diagnostic scale (>= 4)
• At least 6 months of neuropathic pain should be present with a rating of 4 or more on a numeric rating scale from 0 to 10

Exclusion criteria

• Pregnancy or planned pregnancy in the study-period
• Evidence of significant cardiac conduction disturbance
• Current or recent substance abuse problem
• Evidence that would prevent giving informed consent or hinder one*s ability to follow through with the study based on the attending physicians clinical judgment (e.g. a serious psychological disorder, language difficulties)
• No informed consent

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-02-2011
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	23-12-2010
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL33024.048.10