Spinal cord stimulation for treating neuropathic pain after chemotherapy / radiotherapy; a pilot study

Published: 16-12-2011
Last updated: 19-03-2025

To demonstrate that SCS is capable of treating otherwise refractory neuropathic pain after chemotherapy / radiotherapy.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON47554

Source
ToetsingOnline

Brief title
SCS for post-cancer neuropathy, SCS002p

Condition

- Peripheral neuropathies

Synonym
neuropathic pain caused by chemotherapy / radiotherapy

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: stichting Neurobionics Foundation

Intervention

Keyword: chemo therapy, neuropathic pain, radiotherapy, spinal cord stimulation

Outcome measures

Primary outcome

Primary outcome measure is the change in neuropathic pain as measured by VAS score after 6 months of SCS.

Secondary outcome

Secondary objectives are an evaluation of the efficacy of SCS treatment in patients with post cancer neuropathic pain as measured by change in pain intensity at all visits, and an evaluation of following health outcome measures: McGill Pain Questionnaire, EuroQoL 5D, HADS, patient's satisfaction, changes in pain medication, changes in EEG features.

Study description

Background summary

Several publications have shown that post-cancer neuropathic pain is a common and disabling side effect of chemotherapy and radiotherapy and yet medical treatment of this pain remains largely ineffective. Limited literature is available on the effects of spinal cord stimulation (SCS) in this type of neuropathic pain, nevertheless a case report on two patients demonstrated good results. A pilot study to assess the effect of SCS in post-cancer neuropathic pain will be relevant. Depending on the outcome of this pilot study on post-cancer neuropathic pain, an RCT will be implemented.

Study objective

To demonstrate that SCS is capable of treating otherwise refractory neuropathic pain after chemotherapy / radiotherapy.

Study design

The study is an open, prospective, pilot study

Intervention

All patients will have a trial stimulation period with an external SCS pulse generator. If the trial is successful (> 50% pain reduction) an SCS system will be implanted.

Study burden and risks

The questionnaires and EEG measurement are not associated with any risk. Spinal cord stimulation refers to electrical stimulation of the spinal cord and is considered a treatment that is minimally invasive, reversible, and adaptable. The targeted study population consists of patients who have exhausted conventional/conservative methods of relieving chronic pain due to post-cancer neuropathy.

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

- Peripheral neuropathic pain in lower extremities that exists for more than 6 months and is due to chemotherapy / radiotherapy.
- Patient cannot be treated further otherwise according to patients* medical specialist.
- The pain-sensation on a visual analogue scale is 5 or more.

Exclusion criteria

- Psychological problems that requires treatment.
- Insufficient cooperation by patient (motivation, insight or communication).
- Coagulation irregularities/ Anti-coagulants.
- Life expectancy less than 1 year.
- Local infection at the site of the incision
- Implanted pacemaker, ICD or other neuromodulation system

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-09-2012
Enrollment:	11
Type:	Actual

Medical products/devices used

Generic name:	spinal cord stimulator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-12-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-02-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-12-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-04-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-03-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-11-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 25222
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL37975.044.11
OMON	NL-OMON25222