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

No registrations found.

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

Summary

ID

NL-OMON25222

Source
NTR

Brief title
SCS002p

Health condition

neuropathic post-cancer pain,

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Change in neuropathic pain as measured by VAS score after 6 months of SCS.

Secondary outcome

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 other health outcome measures.

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. A pilot study to assess the effect of SCS in post-cancer neuropathic pain will be relevant. This study is an open, prospective, pilot study. 11 patients with refractory neuropathic pain caused by chemotherapy / radiotherapy will be included. They should be eligible for spinal cord stimulation and have VAS scores for pain > 5. 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. Evaluation visits (to acquire pain scores and other health outcome measures) will occur at 1, 3 and 6 months after implantation. Primary outcome measure is the change in neuropathic pain as measured by VAS score after 6 months of SCS. After completion of the 6 months study treatment period, all patients will be followed in accordance with standard medical care.

Study objective

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

Study design

Evaluation visits (to acquire pain scores and other health outcome measures) will occur at 1, 3 and 6 months after implantation.

After completion of the 6 months study treatment period, all patients will be followed in accordance with standard medical care.

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. After 1, 3 and 6 months of SCS the patients have follow up visits where pain scores and other health outcome measures are acquired.

Contacts

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Eligibility criteria

Inclusion criteria

1. Peripheral neuropathic pain in lower extremities that exists for more than 6 months and is due to chemotherapy or radiotherapy;

2. Patient cannot be treated further otherwise according to patients' medical specialist;

3. Physiotherapy and/or manual therapy, lumbar sympathetic ganglion and/or RIS-blocks and/or oral medication give insufficient pain relief or unacceptable side-effects;

4. The pain-sensation on a visual analogue scale is 5 or more (recording both for day and night time).

Exclusion criteria

1. Age < 18 years;

2. Psychological problems that requires treatment;

3. Addiction (i.e. compulsory) to: drugs, alcohol, medication;

4. Insufficient cooperation by patient (motivation, insight or communication);

5. Coagulation irregularities/ Anti-coagulants;

6. Immune compromised;

7. Life expectancy less than 1 year;

8. Pregnancy;

9. Local infection at the site of the incision;

10. Implanted pacemaker, ICD or other neuromodulation system.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2012
Enrollment:	11
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 47554
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3055
NTR-old	NTR3203
CCMO	NL37975.044.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON47554

Study results

Summary results
N/A