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

Gepubliceerd: 08-12-2011 Laatst bijgewerkt: 19-03-2025

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

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON25222

**Bron**
NTR

**Verkorte titel**
SCS002p

**Aandoening**

neuropathic post-cancer pain,

### Ondersteuning

**Primaire sponsor:** Medisch Spectrum Twente
**Overige ondersteuning:** Medisch Spectrum Twente

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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

### Onderzoeksopzet

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.

### Onderzoeksproduct en/of interventie

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.

# Contactpersonen

## Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-01-2012 |
| Aantal proefpersonen: | 11 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47554
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

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

# Resultaten

**Samenvatting resultaten**
N/A