# Comparing patient's preference of dorsal column stimulation versus dorsal root ganglion stimulation in patients with complex regional pain syndrome confined to the knee

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Dorsal column stimulation and dorsal root ganglion stimulation are both proven to be effective as treatment for chronic, neuropathic pain. We want to compare patients preference of stimulation type in patients with chronic, neuropathic pain due to...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Spinal cord and nerve root disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON41087

**Source**
ToetsingOnline

**Brief title**
DCS/DRG Study

### Condition

- Spinal cord and nerve root disorders

**Synonym**
Complex Regional Pain Syndrome, Reflex Sympathetic Dystrophy

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Comparison, Complex Regional Pain Syndrome, Knee, Neurostimulation

## Outcome measures

### Primary outcome

The aim of this study is to compare the effect on chronic pain of two neurostimulation types; DCS and DRG stimulation in a group of patients with chronic pain due to CRPS confined to the knee. Primary objective will be the patient*s preference.

### Secondary outcome

- Pain

- Quality of life

- Functionality of the affected limb

- The effect on inflammation by stimulation

Pain medication utilization will be recorded and tracked during the follow up.

# Study description

### Background summary

Complex regional pain syndrome is a collection of locally appearing painful conditions following a trauma, which mainly occur in the feet or the hands and exceed in both intensity and duration the expected clinical course of the original trauma. The natural history of CRPS is not always positive and can result in permanent disability. Our interest was drawn by a group of patients

with CRPS confined to the knee. Neurostimulation is an accepted, effective and safe way for the treatment of chronic pain. Neurostimulation has already been demonstrated as being effective as treatment for patients with CRPS. CRPS is the second common indication for dorsal column stimulation (failed back surgery being the first one). DCS has his limitations; it is rather nonspecific and places like the knee are difficult to stimulate. In 2011 the first patients received a dorsal root ganglion stimulation device as treatment for their chronic neuropathic pain. Both stimulation devices require a test period; if the patient has clinical significant pain relief during this test period, a definitive implantation can be the next step.

**Study objective**

Dorsal column stimulation and dorsal root ganglion stimulation are both proven to be effective as treatment for chronic, neuropathic pain. We want to compare patients preference of stimulation type in patients with chronic, neuropathic pain due to CRPS confined to the knee.

**Study design**

The study consists of two phases. Patients will be screened based upon the inclusion and exclusion criteria, consented and enrolled into the study. The patients are included for both phases of the study. Fifteen patients will then be assessed for baseline measurements of several secondary outcomes.

Phase 1.
Temporary Trial Stimulation. Patients will trial the two neurostimulation systems during a period of 16 days. Day 1 will be the day when the intervention takes place. Both types of stimulationleads will be implanted during the same time, during the same procedure. Day 1-4 will be without any stimulation; in this way the patient is given some time to recover from the intervention. Days 5-9 and days 12-16 will be the days when one of each stimulation is active. A randomisation based on a computer program takes place for each patient to decide the order of stimulation. During days 10-11 there will be a wash out period; a period without any stimulation. Every patient need to document the pain relief and satisfaction for each stimulation during phase 1 in a patient diary. If the eligible patients agrees to have a definitive implantation, they will undergo another surgical procedure following phase 1 within two weeks, in which the definitive neurostimulation will be fully implanted.
Phase 2.
Long term Follow Up. During the long term follow up the patients will be visiting the department at one, three, six and twelve months after the implant. In case a patient was a *double-negative*, he/she will still be visiting the department the same time as the implanted patients. The double-negatives will than serve as controls. During the visits at 3 and 12 months after implant the patient will undergo the same measurements as they already did at baseline. At

the 6 months after implant visit, the patient will undergo a FDG/PET CT scan for the second time, to see if the stimulation has any effect on the inflammation.

### Intervention

Placement of two different types of neurostimulation leads: corsal column stimulation leads and dorsal root ganglion stimulation leads. After the trial period of 16 days, the patient will undergo a next operation within one week for definitive placement of the neurostimulator.

### Study burden and risks

The potential benefits of the therapy include significant pain relief, increased quality of life, increased function, and reduced medicinal intake for pain management. Both neurostimulation devices are usual standard care in reducing chronic pain. The possibility of trying both systems, in randomised order, in the same patient, before choosing which stimulation will be implanted after clinically relevant pain relief is not usual standard care. The leads will be placed during the same procedure, at the same time. No additional risks are expected. During the trial period the patients will have to visit the Erasmus MC two times extra; during this visit one system will be turned off and the other one will be turned on. The FDG/PET-CT scan will be performed with radioactive load, but the amounts are negligible.

## 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

- Over one year CRPS confined to the knee, diagnosed according to the Budapest Criteria Set
- Minimum age of 18 years
- No improvement of symptoms after at least one year of treatment according to the Dutch guidelines for CRPS in primary care
- Pain intensity of at least 50 mm measured on a visual analogue scale 0-100 mm

### Exclusion criteria

- Previous neurostimulation
- Depression or an anxiety disorder
- Pregnancy or pregnancy desire within one year
- Patients who are not able to complete the questionnaires
- Body Mass Index >35
- Life expectancy <1 year
- Anticoagulant drug therapy or disturbed coagulation
- ICD and Pacemaker
- Immune-compromised patients
- Drugs/Medication/Alcohol addiction

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Crossover |
| Masking: | Open (masking not used) |

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| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 16-09-2014 |
| Enrollment: | 15 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 31-07-2014 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

## 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: 22933
Source: NTR
Title:

### In other registers

| Register | ID |
|---|---|
| CCMO | NL48584.078.14 |
| OMON | NL-OMON22933 |