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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22933

Source
NTR

Brief title
DCS/DRG Study

Health condition

Complex Regional Pain Syndrome, neuromodulation

Sponsors and support

Primary sponsor: Erasmus MC University Medical Center Rotterdam
Source(s) of monetary or material Support: An investigator initiated study which is financially supported with a grant from Spinal Modulation

Intervention

Outcome measures

Primary outcome

Patients' preference

Secondary outcome

- Pain

- Quality of life

- Functionality of the affected limb

- Physical functioning

- The effect on inflammation by stimulation

Study description

Background summary

Rationale: 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 (DCS versus DRG stimulation) in patients with chronic, neuropathic pain due to CRPS confined to the knee.

Objective: The purpose of this study is to compare DCS with DRG stimulation in treating chronic pain due to CRPS, to determine the preference of treatment of patients diagnosed with CRPS confined to the knee.

Study design: This is a prospective, observational study with a parallel design comparing two types of neurostimulation in randomised order and follow up.

Study population: Fifteen patients (> 18 years old) diagnosed with CRPS confined to the knee with no improvement of symptoms after at least one year of conservative treatment according to the Dutch guidelines for CRPS in primary care.

Treatment: Patients will receive two types of stimulation leads: one DCS lead and two DRG stimulation leads. Randomization will decide which stimulation will be turned on by the

physician first and which stimulation will be turned on second. Patients will have one stimulation during five days, then a wash our period of two days (period without any stimulation), and continue with the second stimulation during five days. Patients with successful trial stimulation with either stimulation will receive a fully-implantable system of the stimulation which is preferred by the patient and will be followed during 12 months.

Main study parameters/endpoints: The main endpoint of the study is to determine which of two types of stimulation, both possible as therapy in reducing chronic pain, is preferred in a group of patients with chronic pain due to CRPS confined to the knee. Pain, health-related quality of life, physical function and patient satisfaction with the treatment will also be assessed.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
The potential benefits of the therapy include significant pain relief, increased quality of life, increased function, and reduced medicinal intake for pain management. There are no perceived risks to the patients as both treatments are routinely offered to treat chronic pain.

Study objective

Dorsal column stimulation (DCS) and dorsal root ganglion (DRG) stimulation are both proven to be effective as treatment for chronic, neuropathic pain. We want to compare patients preference of stimulation type (DCS versus DRG stimulation) in patients with chronic, neuropathic pain due to CRPS confined to the knee. The purpose of this study is to compare DCS with DRG stimulation in treating chronic pain due to CRPS, to determine the preference of treatment of patients diagnosed with CRPS confined to the knee

Study design

The secondary outcomes will be measured at 1 month, 3 months, 6 months and 12 months after definitve implantation.

Intervention

A qualified physician will implant one lead for DCS and two leads for DRG stimulation at the same time, during the same procedure, under local anesthesia. The implantation place of the leads differ from each other: the DCS lead will be implanted above the dorsal column, the DRG stimulation leads will be implanted above the DRG. The leads can’t connect to each other. All leads will be sutured to the skin with soft tissue anchors and the external lead exit point will be protected according to the usual standard of care. Day 2-7 will be stimulation 1, during days 8-9 there will be a wash out period (a period without any stimulation) and days 10-14 will be stimulation 2. A randomization based on a computer program decides the order of stimulation. The physician will take care of turning on the stimulation and the switch of the type of stimulation. Every patient needs to document the pain relief and satisfaction for each

stimulation in a patient diary. If the patient reports clinically significant pain relief from one of the stimulation types, the patient will get that stimulation type implanted. If both types of stimulation give clinically significant pain relief, the patient is allowed to choose the stimulation he/she prefers. According to the usual standard of care with respect to neurostimulation, clinically significant pain relief is defined as at least 50% reduction of pain due to the stimulation.

Contacts

Public
Erasmus MC, Room Ba-430.
Catelijne van Bussel
Postbus 2040
Rotterdam 3000CA
The Netherlands
Scientific
Erasmus MC, Room Ba-430.
Catelijne van Bussel
Postbus 2040
Rotterdam 3000CA
The Netherlands

Eligibility criteria

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

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2014
Enrollment:	15
Type:	Actual

Ethics review

Positive opinion

Date:	19-01-2016

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41087
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5542
NTR-old	NTR5662
CCMO	NL48584.078.14
OMON	NL-OMON41087

Study results