Comparing patients' 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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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22933

Bron
NTR

Verkorte titel
DCS/DRG Study

Aandoening

Complex Regional Pain Syndrome, neuromodulation

Ondersteuning

Primaire sponsor: Erasmus MC University Medical Center Rotterdam
Overige ondersteuning: An investigator initiated study which is financially supported with a grant from Spinal Modulation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Patients' preference

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	15
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	19-01-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41087
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten