The influence of low frequency stimulation with a Dorsal Root Ganglion stimulator on peripheral blood flow in patients with Complex Regional Pain Syndrome and vasomotor disturbances.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27386

Source
NTR

Brief title
TBA

Health condition

Complex Regional Pain Syndrome

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Erasmus MC

Intervention

Outcome measures

Primary outcome

Difference in skin temperature between the affected and contralateral extremity for each used frequency

Secondary outcome

Demographic variables

Study description

Background summary

Complex regional pain syndrome (CRPS) is a complication after trauma or surgery. CRPS is characterized by a continuing regional pain in a distal extremity, often combined by vasomotor, sudomotor and motor/throphic disturbances. In the chronic phase of CRPS the affected extremity can change into a cold extremity induced by vasomotor disturbances that cause a decrease in blood flow. Spinal cord stimulation (SCS) is effective on pain in CRPS. Besides SCS also turns out to induce peripheral vasodilatation. However SCS has also some limitations that were not found in DRG stimulation. Clinical observations, however, show a positive effect on vasomotor dysfunction of Dorsal Root Ganglion (DRG) stimulation in CRPS, at least in a part of the patients. This effect seems to be frequency dependent.
The objective of this study is to investigate which frequencies of DRG stimulation have an influence on the peripheral blood flow of the affected extremity in patients with CRPS and vasomotor disturbances and should thereby be further investigated.

Study objective

Low frequency stimulation causes vasodilation in the affected extremity of patients with CRPS

Study design

Single measurement

Intervention

Different frequencies of stimulation with a DRG stimulator. The patients already have had a DRG stimulator surgically implanted as standard care for treatment of CRPS. The frequencies used as intervention in this experiment are in the range of standard treatment.

Contacts

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Eligibility criteria

Inclusion criteria

• Patients diagnosed with CRPS according to the new IASP criteria
• Patients must have vasomotor disturbance; the skin temperature of the affected extremity is at least 1°C colder than skin temperature of the contralateral extremity. This will be measured using a thermography imaging camera and determined using MatLab
• Patients must have a DRG stimulator for treatment of CRPS, that has been implanted at least three months before inclusion
• Clinically the contralateral extremity must be without signs or symptoms in a way that it can be used as a control.

Exclusion criteria

• Age < 18 years
• Patients diagnosed with other disease that influences the peripheral blood flow
• Patients using medication that influences peripheral blood flow
• DRG stimulator implanted within three months before inclusion

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2020
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	30-01-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47944
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8342
CCMO	NL67598.078.18
OMON	NL-OMON47944

Study results