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.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON47944

Source
ToetsingOnline

Brief title
LoFreD

Condition

- Peripheral neuropathies

Synonym
Complex Regional Pain Syndrome, posttraumatic 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: Complex Regional Pain Syndrome (CRPS), Dorsal Root Ganglion stimulation, Pulse frequency, Vasomotor disturbances

Outcome measures

Primary outcome

The main endpoint of this study is the effect on peripheral blood flow.

Secondary outcome

The secondary parameters of this study are the mitoPO2 and mitoVO2.

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 Dorsal Root Ganglion (DRG) stimulation. Clinical observations, however, show a positive effect on vasomotor dysfunction of DRG stimulation in CRPS, at least in a part of the patients. This effect seems to be frequency dependent. The pathophysiology of vasomotore disturbances in CRPS is still not completely understood. Endothelial dysfunction is one of the underlying mechanismes of vasomotor disturbances in CRPS. Mitochondrial dysfunction is associated with endothelial dysfunction in cardiovascular diseases. It could be possible that mitochondrial dysfunction also plays a role in the pathogenesis of vasomotor disturbances in CRPS. The COMET monitor assesses Cellular Oxygen METabolism by measuring cutaneous mitoPO2 and mitoVO2 in humans.

Study objective

The objective of this study is to investigate if low frequency stimulation with a DRG stimulator effects peripheral blood blow in patients with CRPS and vasomotor disturbances. The secondary goal is to investigate if the frequency with the best effect in peripheral blood flow also influences the mitoPO2 and mitoVO2.

Study design

A prospective pilot study.

Intervention

Different frequencies of stimulation with a DRG Stimulator.

Study burden and risks

There may be a direct benefit from this intervention. If during the experiment a frequency is found that gives a better effect for the patient than the current settings, the settings of the DRG Stimulator will be adjusted. At the long term this study may contribute to better treatment of vasomotor disturbances in CRPS. There can be a burden for patients because setting off the DRG-stimulator for a short period (30 minutes wash-out) and changes in the stimulation frequency can temporarily and reversibly cause an increase in pain, a change in skin temperature or skin color, or swelling in the affected extremity due to changes of the settings of the DRG stimulator. The intracellular oxygen measurement is a non-invasive measurement technique. The specific discomfort for the subject is that aan aminolevulic acid containers-plaster is applied that makes the skin sensitive for light. This plaster is applied on the skin 5-8 hours before the measurement. The measurement of mitoPO2 and mitoVO2 can may contribute to a better understanding of the pathogenesis of vasomotor disturbances in CRPS.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molenwaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molenwaterplein 40

Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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

NB: of patients suffer from mitochondrial disease or porphyria the measurement of mitoPO2 and mitoVO2 will be leaved out.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-06-2023
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	21-03-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	15-05-2020
Application type:	Amendment
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: 27386
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL67598.078.18
OMON	NL-OMON27386