

Non-invasive measurement of mitochondrial oxygenation in patients with Complex Regional Pain Syndrome

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The primary objective is to investigate if there is altered mitochondrial oxygenation and consumption in the skin cells of the affected extremity in patients with CRPS by measuring the mitoPO2 and mitoVO2.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Observational non invasive

Summary

ID

NL-OMON47977

Source

ToetsingOnline

Brief title

COMET in CRPS

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: COMET, Complex Regional Pain Syndrome, Mitochondrial oxygenation

Outcome measures

Primary outcome

Baseline mitoPO2 of the affected and contralateral extremity and MitoVO2 of the affected and contralateral extremity.

Secondary outcome

- Demographic parameters such as: age, sex, smoking and consumption of alcohol
- General medical history and medication use
- CRPS severity score
- Videothermography image of the affected and contralateral extremity

Study description

Background summary

Complex regional pain syndrome (CRPS) is a complication after trauma or surgery. CRPS is characterized by chronic pain in a distal extremity, usually combined with abnormal sensory, autonomic, motor and/or trophic changes. Temperature asymmetry is common in CRPS. The pathophysiology of vasomotor disturbances in CRPS is still not completely understood. Endothelial dysfunction is one of the underlying mechanisms 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 CRPS. The COMET monitor assesses Cellular Oxygen METabolism by measuring cutaneous mitoPO2 and mitoVO2 in humans.

Study objective

The primary objective is to investigate if there is altered mitochondrial oxygenation and consumption in the skin cells of the affected extremity in patients with CRPS by measuring the mitoPO2 and mitoVO2.

Study design

A single-center feasibility study in patients with CRPS.

Study burden and risks

The intracellular oxygen measurement is a non-invasive measurement technique. The specific discomfort for the subject is that an aminolevulinic acid containing-plaster is applied that makes the skin sensitive for light. This plaster is applied on the skin 5-8 hours before the measurement. The participants will not benefit directly from participation of the study. It takes patients about half an hour of time. This study can may contribute to a better understanding of the pathogenesis of vasomotor disturbances in CRPS. The risk in this study is negligible. Thereby the group related benefits counterweight the risks in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- Diagnosed with CRPS according to the new IASP criteria. We will only include patients that still meet these criteria.
- Clinically the contralateral extremity must be without signs or symptoms in a way that it can be used as a control
- Signed informed consent

Exclusion criteria

- < 18 years of age
- Presence of mitochondrial disease
- Porphyria

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 16-01-2020

Enrollment: 10

Type: Actual

Ethics review

Approved WMO

Date: 22-08-2019
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

No registrations found.

In other registers

Register	ID
CCMO	NL68809.078.19