

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

No registrations found.

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

Summary

ID

NL-OMON26528

Source

Nationaal Trial Register

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

MitoPO2 and mitoVO2

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.

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 objective

Mitochondrial oxygenation and consumption are altered in the affected extremity of patients with CRPS.

Study design

Single measurement

Contacts

Public

Erasmus MC
Else Bijl

+31650032166

Scientific

Erasmus MC
Else Bijl

Eligibility criteria

Inclusion criteria

Patients with CRPS

- 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

Healthy controls

- Signed informed consent

Exclusion criteria

Patients with CRPS

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

Healthy controls

- < 18 years of age
- Presence of mitochondrial disease
- Porphyria
- (Consideration of) diagnosis of CRPS in history

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: Recruitment stopped
Start date (anticipated): 16-01-2020
Enrollment: 24
Type: Actual

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

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8341
CCMO	NL68803.078.19

Study results