

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	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 mitoPO<sub>2</sub> and mitoVO<sub>2</sub> 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 mitoPO<sub>2</sub> and mitoVO<sub>2</sub>.

### 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