# Near-infrared spectroscopy in cold type Complex Regional Pain Syndrome

Published: 29-10-2015
Last updated: 19-04-2024

The primary objective of this study is to compare muscle blood flow and oxygen consumption, as measured by NIRS, in patients with cold type CRPS and healthy controls. The secondary objectives of this study are to compare muscle oxygenation (tissue...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON42462

**Source**
ToetsingOnline

**Brief title**
NIRS in CRPS

### Condition

- Other condition
- Tissue disorders NEC

**Synonym**
Complex regional pain syndrome, Reflex Sympathetic Dystrophy Syndrome (RSDS), Sudeck's atrophy

**Health condition**

Skeletspier metabolisme en doorbloeding bij koude complex regionale pijnsyndroom

**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, Muscle bloodflow, Muscle metabolism, Near-infrared spectroscopy

## Outcome measures

### Primary outcome

The main study parameters consist of the within person and between person

difference in muscle oxygen consumption and blood flow in patients with cold

type CRPS and controls. These differences are tested during rest and exercise.

### Secondary outcome

Secondary study parameters will be:

- The tissue saturation index (TSI) during rest and exercise. This is an

estimate of the tissue oxygen saturation in percentage.

- The rise in oxyhemoglobin during reactive hyperemia. This is measured during

rest and exercise.

# Study description

### Background summary

Complex regional pain syndrome (CRPS) is a clinical disorder characterized by severe pain in an injured limb which is accompanied by sensory, motor, vasomotor, trophic and sudomotor changes. A precise pathophysiological mechanism for CRPS is yet to be revealed. A new hypothesis has been proposed which suggests that deep tissue (i.e. muscle, bone and nerve) microvascular injury, inflammation and ischemia might be the driving force for (cutaneous) findings in CRPS (e.g. allodynia). Based on this theory, the aim of this study is to examine muscle oxygen consumption and blood flow, using near-infrared

spectroscopy (NIRS), in the skeletal muscles of patients with cold type CRPS as compared to controls. Cold type CRPS is characterized by bilateral temperature asymmetry, bilateral perfusion differences and atrophy of skin, muscle and bone. The results of this study could lead to a better understanding of the role of deep tissue pathology in cold type CRPS and could have implications for the diagnoses and management of this syndrome

### Study objective

The primary objective of this study is to compare muscle blood flow and oxygen consumption, as measured by NIRS, in patients with cold type CRPS and healthy controls. The secondary objectives of this study are to compare muscle oxygenation (tissue saturation index, %) and reactive hyperaemia rates during rest and exercise in patients with cold type CRPS and controls.

### Study design

This study is a prospective case-control study.

### Intervention

Both groups will receive a venous and arterial occlusion during the measurements to determine the muscle blood flow and oxygen consumption respectively.

### Study burden and risks

The risks of this study are negligible. The NIRS-device is a non-invasive device which is placed on the skin for the measurements. Arterial occlusions are sometimes considered painful hence precautions such as shortening the length of the occlusion and placing the blood pressure cuff outside the painful area have been taken to avoid any discomfort. The study requires one visit to the outpatient clinic of the Department of Pain Medicine at Erasmus Medical Centre. The study visit will take approximately 2 hours and 45 minutes. There is no direct benefit of participation in this study. This study could lead to a better understanding of the pathophysiology of CRPS and could pave the way for new therapies targeting deep tissue pathology.

## Contacts

**Public**
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230

Rotterdam 3000CA
NL
**Scientific**
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3000CA
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Patients with the diagnosis cold unilateral CRPS of an upper or lower limb according to the Budapest Research Criteria (not applicable in Controls):
Continuing pain, which is disproportionate to any inciting event
Must report at least one symptom in three of the four following categories:
Sensory: reports of hyperesthesia and/or allodynia
Vasomotor: reports of temperature asymmetry and/or skin color changes and/or skin color asymmetry
Sudomotor/edema: reports of edema and/or seating changes and/or sweating asymmetry
Motor/trophic: reports of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin)
Must display at least one sign at time of evaluation in two or more of the following categories:
Sensory: evidence of hyperalgesia (to pinprick) and/or allodynia (to light touch and/or deep somatic pressure and/or joint movement)
Vasomotor: evidence of temperature asymmetry with the affected side being >= 1° colder than the unaffected side.
Sudomotor/edema: evidence of edema and/or sweating changes and/or sweating asymmetry
Motor/trophic: evidence of decreased range of motion and/or motor dysfunction (weakness,

tremor, dystonia) and/or trophic changes (hair, nail, skin).
There is no other diagnosis that better explains the signs and symptoms.
- Age >= 18 years
- Able to provide written informed consent

### Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Known history of peripheral arterial disease (PAD) or suspicion of PAD at intake
- Known history of Diabetes Mellitus
- Other confounding neuropathic conditions i.e. paraplegia and neuropathies due to other causes than CRPS.
- Coagulopathy or use of blood thinners
- Use of vasoactive medications
- Pregnancy

## Study design

### Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Basic science

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 03-08-2015 |
| Enrollment: | 64 |
| Type: | Anticipated |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 29-10-2015 |
| 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 | NL54178.078.15 |