Oxygenation of Affected Limbs in CRPS-I Patients

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The aim is to investigate static and dynamic tissue oxygenation state and skin temperature in patients with CRPS-I and to compare CRPS-I patients with pain patients and healthy controls. The correlation between tissue oxygenation, skin temperature…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43069

Source
ToetsingOnline

Brief title
Oxygenation in CRPS

Condition

- Other condition
- Peripheral neuropathies

Synonym
nerve pain, post traumatic dystrophy

Health condition

Complex Regionaal Pijn Syndroom

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CRPS-I, Oxygenation, Skin temperature

Outcome measures

Primary outcome

Tissue oxygenation in both static and dynamic conditions will be compared between CRPS-affected and unaffected limbs and between CRPS patients, pain controls and healthy controls. Furthermore, differences in tissue oxygenation in static and dynamic measurements and correlations with pain, skin temperature variations, and disease duration will be determined.

Secondary outcome

The correlation between oxygenation and skin temperature with experienced pain, amount of limb movement, and disease duration will be investigated as well.

Study description

Background summary

Pathophysiologic mechanisms of CRPS are not well understood, but vasomotor disturbances are likely to play a role in initiating and maintaining the disease. Research indicates that tissue perfusion and oxygenation might have a causative effect on CRPS; however, whether this is true and to what extent is yet to be determined.

Study objective

The aim is to investigate static and dynamic tissue oxygenation state and skin temperature in patients with CRPS-I and to compare CRPS-I patients with pain patients and healthy controls. The correlation between tissue oxygenation, skin

temperature variation and pain is also investigated.

Study design

This pilot study takes the form of an open prospective and case control study.

Intervention

Oxygen is applied as an intervention to examine and compare its effect on the oxygenation in healthy participants and CRPS patients.

Study burden and risks

Participants are required to visit the VUmc twice. The first meeting, questionnaires are filled in, and baseline measurements of tissue oxygenation and skin temperature are made. The second meeting, follow-up measurements of both are made. In between the two meetings, participants have to wear small thermoregistration buttons and keep diaries regarding pain and use of the buttons. Participation takes approximately seven days, and each meeting is estimated to take 1-1.5 hours. Risks of the study are minimal, as participants are only breathing oxygen during tissue oxygenation measurements which carries negligible risks. Patients do not benefit from participating; however, this study is expected to result in additional knowledge regarding their disease.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion criteria CRPS-I patients:
CRPS-I according to 2012 IASP (Budapest) criteria: Harden RN, Bruehl S, Perez RS, et al. Validation of proposed diagnostic criteria (the "Budapest Criteria") for Complex Regional Pain Syndrome. Pain 2010; 150: 268-274.;Inclusion criteria pain controls:
Patients diagnosed with Radiculopathy with pain in one extremity as main symptom;Inclusion criteria healthy controls: >18 years old, healthy (no neurological, cardiac, pulmonary, renal or vascular diseases diagnosed)

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:;- Age <18
- Not able to give informed consent
- Pregnancy
- History of peripheral vascular disease requiring angioplasty or bypass surgery [5]
- Type 1 or 2 diabetes [5]
- History of systemic vasculitis [5]
- Use of vasoactive medication [5]
[5]: Bellingham GA, Smith RS, Morley-Forster P and Murkin JM. Use of near infrared spectroscopy to detect impaired tissue oxygen saturation in patients with complex regional pain syndrome type 1. Can J Anaesth 2014; 61: 563-570.

Study design

Design

Study type: Interventional

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-09-2016
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Conoxia
Generic name:	Oxygen 100%
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	20-05-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-06-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2016-001353-41-NL
CCMO	NL56714.029.16