Pulse Transit Time in patients with Complex Regional Pain Syndrome

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To develop pulse transit time into a diagnostic device which can be used to assess an altered cold/heat mediated vasomotor response (CHMV) (central component) and the flow-mediated dilatation (FMD) (peripheral component) in CRPS patients.

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

Summary

ID

NL-OMON36582

Source
ToetsingOnline

Brief title
PTT in CRPS patients

Condition

- Peripheral neuropathies
- Vascular disorders NEC

Synonym
reflex sympathetic 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,BSIK03016

Intervention

Keyword: Complex Regional Pain Syndrome (CRPS), Pulse transit time (PTT)

Outcome measures

Primary outcome

Difference in PTT, as a result of cold-heat mediated vasomotor function within subjects and between subjects. Difference in PTT, as a result of flow mediated dilatation within subjects and between subjects. Standard error of measurement and smallest detectable difference of PTT in controls and patients.

Relationship between severity of symptoms of CRPS patients and PTT measurement in patients.

Secondary outcome

Relationship between severity of symptoms of CRPS patients and PTT measurement in patients.

Study description

Background summary

Based on previous findings, the blood circulation in a CRPS1 involved limb can be altered due to vasomotor dysfunction. This vasomotor dysfunction can be caused by central and/or peripheral mechanisms. Clinically it is difficult to determine the involved mechanism, prohibiting effective treatment. Therefore we need equipment that can more reliable determine the cause of vasomotor dysfunction, allowing a mechanism based treatment. The aim of this study: is pulse transit time (PTT) a reliable tool to provide information about a mechanism involved in vasomotor dysfunction in patients with CRPS1?

Study objective

To develop pulse transit time into a diagnostic device which can be used to assess an altered cold/heat mediated vasomotor response (CHMV) (central component) and the flow-mediated dilatation (FMD) (peripheral component) in

CRPS patients.

Study design

Observational single centre case-control study.

Study burden and risks

The risks are negligible. In this study we take measurement on the skin. Total research will request one visit of approx. 1 hour and 45 minutes. There is no direct benefit for the patient to participate in the study. Furthermore these methods might elucidate aspects of the pathophysiology involved in CRPS.

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

18 year and older
Diagnosed as CRPS according to the IASP criteria
One CRPS involved upper limb

Exclusion criteria

Without illness that effects vasomotor functioning
o Cardiovascular diseases
o Peripheral vascular disease
o Diabetes
o Muscle or skeletal injuries in upper limb
Incapacitated subjects
Haemopoetic disease

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-12-2009
Enrollment:	114
Type:	Actual

Ethics review

Approved WMO Date:	27-10-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-02-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-01-2012
Application type:	Amendment
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	NL27847.078.09