Validation of the cantharidin-induced blister method in Complex Regional Pain Syndrome

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This pilot study will be performed to investigate whether the cantharidin-induced blister method is a useful alternative for the vacuum blister method in patients with acute or chronic CRPS.Replacement of the vacuum blister method by the filter disc...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON30083

Source
ToetsingOnline

Brief title
Validation of skin blister method in CRPS

Condition

- Autoimmune disorders
- Fractures

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: cantharidine, CRPS, skin blister, vacuum suction

Outcome measures

Primary outcome

Bioactive substances: cytokines, nitric oxide and other vasoactive mediators.

Secondary outcome

none

Study description

Background summary

In research with Complex Regional Pain Syndrome (CRPS) patients, bioactive substances are being measured in blister fluid from the involved hand or foot in comparison with the non-involved hand or foot. This reflects disease activity and displays effectiveness of pharmaceutical intervention during the course of the disease.
In order to replace the so far standard vacuum blister method by a more convenient method, the usefulness should be tested simultaneously, both in healthy controls and CRPS patients in the acute (inflammatory) phase and the chronic (trophic) phase of the disease. It is not known whether locally formed mediators are reflected similar by these two methods.

Study objective

This pilot study will be performed to investigate whether the cantharidin-induced blister method is a useful alternative for the vacuum blister method in patients with acute or chronic CRPS.
Replacement of the vacuum blister method by the filter disc method could be more appropriate for the patient and result in better blisters with higher quantities.

Study design

In a parallel study blister fluid obtained after induction of cantharidin or vacuum suction, measurements to compare the concentrations of bioactive substances will be performed.

Study burden and risks

A disadvantage could be the application of another blister which has been generated by the cantharidin containing filter disc. The healing of this blister should be faster as the vacuum suction blister, which in some cases reveal scars.
The simultaneous induction of these two types of blisters is not time consuming nor expected to induce risk factors.

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

acute or chronic CRPS

Exclusion criteria

use of immunosuppressives

Study design

Design

Study type:	Observational 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):	11-05-2006
Enrollment:	30
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	26-04-2006
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	NL11557.078.06