Measurement of cytokines in cantharidin bisters

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The primary goal of this study is to te verify that it is possible to measure te concentrations of cytokines IL-1α, IL-1RA en IL-8 in the fluid of a blister that is applied tot the skin of healthy volunteers. using cantharidin. In the future we wish...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON31695

Source
ToetsingOnline

Brief title
Measurement of cytokines in cantharidin bisters

Condition

- Diabetic complications

Synonym
diabetic neuropathic ulcers / diabetic foot sores; Charcot osteoarthropathy / Charcot foot

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Blisters, Cantharidin, Cytokines

Outcome measures

Primary outcome

The primary goal of the study are the concentrations of cytokines IL-1α, IL-1RA

en IL-8 as measured in the blister fluid.

Secondary outcome

NVT

Study description

Background summary

1. Foot ulcers are a feared complication of diabetes mellitus and occur mainly in polyneuropathy patients. We assume that in polyneuropathy patients the inflammatory response to exogenic stimuli is decreased which predisposes to the development of ulcers and infections.
2. Charcot osteoarthropathy is a rare but very invalidating complication of (diabetic) polyneuropathy, often resulting in a deformed foot. We assume that an excessive inflammatory response, in which pro-inflammatory cytokines play a role, to exogenic stimuli is the underlying mechanism in the development of a acute Charcot foot.

Study objective

The primary goal of this study is to te verify that it is possible to measure te concentrations of cytokines IL-1α, IL-1RA en IL-8 in the fluid of a blister that is applied tot the skin of healthy volunteers. using cantharidin. In the future we wish to use this knowledge for developing a method for:
1. testing the hypothesis that in polyneuropathy patients the inflammatory response to exogenic stimuli is decreased.
2. testing the hypothesis that the acute Charcot foot develops as a result of a excessive inflammatory response.

Study design

Pilotstudie (n=6). 25 µl of 0.1% cantharidin solution is applied to the skin of

the upper arm of healthy volunteers. Afterwards a blister will arise. At t=24h the bister will be perforated and the blister fluid will be collected using a pipet. The blister fluid will be kept at a temperature of -80°C and more later concentrations of cytikines IL-1α, IL-1RA and IL-8 will be performed using ELISA.

Study burden and risks

We don't expect any risks for the volunteers. Cantharidin is prescriped more than 1 million times without severe side effects.

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

Age: 18-27
Body mass index within the range of 18-30 kg/m^2

Exclusion criteria

History of lymphangitis
Skin conditions like psoriasis or eczema
Diabetes mellitus
Cancer
Muscle disorders
Upper extremity fractures
Alcohol or drug abuse
Gravidity
Change of weight of more than 4 kg within the last 4 weeks

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2008
Enrollment:	6
Type:	Anticipated

Ethics review

Approved WMO

Date:	29-08-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL21209.068.07