Measurement of cytokines after pressure application.

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The primary goal of this study is to obtain basal knowledge about cytokine concentration in healthy volunteers, after pressure application. In the future we wish to use this knowledge for developing a method for:1. determining a patients risk of...

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

Summary

ID

NL-OMON31763

Source
ToetsingOnline

Brief title
Measurement of cytokines after pressure application.

Condition

- Diabetic complications
- Epidermal and dermal conditions

Synonym
Decubitus (bedsores), Neuropathische voetulcera (footsores)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cytokines, pressure, Sebutape

Outcome measures

Primary outcome

The primary study parameters are the measured cytokine concentrations (pg/ml)

(after pressure application to the skin).

Secondary outcome

The secondary study parameter is the correlation between the time expired after

ending the pressure application and the measured cytokine concentrations

(pg/ml).

Study description

Background summary

1. Decubitus is a common disorder which causes a lot of harm and costs. There is a need of a non-invasive method for detecting patients at risk for developing decubitus. Pro-inflammatory cytokines that are released after mehanical loading are potentially markers for detecting patients at risk.
2. 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 external stimuli is decreased which predisposes to the development of ulcers and infections.
3. 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 obtain basal knowledge about cytokine concentration in healthy volunteers, after pressure application. In the future we wish to use this knowledge for developing a method for:
1. determining a patients risk of decubitus,

2. confirming the hypothesis that in polyneuropathy patients the inflammatory response to external stimuli is decreased.
3. confirming the hypothesis that the acute Charcot foot develops as a result of a excessive inflammatory response.

Study design

Pilotstudy (n=12). The tests will take 2 aftertoons, each of 4,5 hours. During the first afternoon 100 mmHg of mechanical pressure will be applied to the skin of the arm of healthy volunteers for 2 hours using a an apparatus with an indenter that can apply standardized pressure. Afterwards cytokine measurements will be performed at 5 different times using Sebutapes which are applied to the area of pressure. On the second afternoon (about a week after the first afternoon) the non-dominant will be loaded for 1 hour with 200 mmHg. After that the dominant arm will be loaded with 100 mmHg.

Study burden and risks

The vollunteers are not exposed tot real risks by cooperating in this study. Earlier studies have shown that the pressure we will apply causes no harm to the skin. Moreover, the mechanical pressure that will be applied does not exceed the pressure that we all are exposed to in our daily lives.

Contacts

Public
Academisch Ziekenhuis Maastricht

Postbus 5800
6202 AZ Maastricht
Nederland
Scientific
Academisch Ziekenhuis Maastricht

Postbus 5800
6202 AZ Maastricht
Nederland

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

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):	01-01-2008
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO Date:	10-12-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-04-2008
Application type:	Amendment
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	NL20191.068.07