Measurement of cytokines with Sebutapes after loading of the foot.

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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 confirming the hypothesis that in...

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

Summary

ID

NL-OMON32566

Source
ToetsingOnline

Brief title
Measurement of cytokines with Sebutapes after loading of the foot.

Condition

- Diabetic complications

Synonym
diabetic foot ulcera, 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, Foot, Loading, Sebutapes

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

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.

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 confirming the hypothesis that in polyneuropathy patients the inflammatory response to exogenic stimuli is decreased.

Study design

Pilotstudy (n=20). 100 mmHg of mechanical pressure will be applied to the skin of the foot of healthy volunteers 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.

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

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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

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:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	06-05-2009

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	NL23918.068.08