Measurement of cytokines after pressure application.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26199

Source
Nationaal Trial Register

Brief title
Measurement of cytokines after pressure application.

Health condition

1. Decubitus;

2. diabetic foot ulcers (NLD: diabetische voet ulcera);

3. Charcot osteoarthropathy.

Sponsors and support

Primary sponsor: Academisch ziekenhuis Maastricht
Afdeling Endodrinologie (prof.dr. N.C. Schaper)
Postbus 5800
6206 AZ Maastricht (NL)
Source(s) of monetary or material Support: Academisch ziekenhuis Maastricht
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Intervention

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

Background of the study:

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 exogenic 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.

Objective of the study:

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 exogenic 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). 100 mmHg of mechanical pressure will be applied to the skin of the arm 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 population:

12 healthy vollunteers. Age between 18 and 27.

Primary study parameters/outcome of the study:

The primary study parameters are the measured cytokine concentrations (pg/ml) (after pressure application to the skin).

Secundary study parameters/outcome of the study:

The secondary study parameter is the correlation between the time expired after ending the pressure application and the measured cytokine concentrations (pg/ml).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):
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.

Study objective

There is an increase in concentrations of cytokines IL-1alpha, IL-1RA and IL-8 (as measured using Sebutapes) in the skin of the arm in healthy volunteers after mechanical loading of the skin, compared with an control measurement.

Study design

After mechanical pressure application cytokine measurements will be performed at t=0, t=30 minutes, t=60 minutes, t=120 minutes and t=24 hours.

Intervention

100 mmHg of mechanical pressure will be applied to the skin of the arm 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.

Contacts

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Eligibility criteria

Inclusion criteria

1. BMI within 18 and 30 kg/m2;

2. age between 18 and 27.

Exclusion criteria

1. Skin diseases like psoriasis or eczema;

2. Diabetes mellitus;

3. Cancer;

4. Muscle disorders;

5. Fractures of the upper extremity;

6. Alcohol or drug abuse;

7. Gravidity;

8. Change of weight >4 kg in the last 4 weeks.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2008
Enrollment:	12
Type:	Actual

Ethics review

Positive opinion

Date:	23-11-2007
Application type:	First submission

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
NTR-new	NL662
NTR-old	NTR1167
Other	MEC : MEC 07-2-097
ISRCTN	Wordt niet aangevraagd/Observational study

Study results

Summary results

N/A