

Measurement of cytokines after pressure application.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26199

Bron

Nationaal Trial Register

Verkorte titel

Measurement of cytokines after pressure application.

Aandoening

1. Decubitus;
2. diabetic foot ulcers (NLD: diabetische voet ulcera);
3. Charcot osteoarthropathy.

Ondersteuning

Primaire sponsor: Academisch ziekenhuis Maastricht

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Overige ondersteuning: Academisch ziekenhuis Maastricht

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 mechanical 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).

Secondary 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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. BMI within 18 and 30 kg/m²;
2. age between 18 and 27.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestopt
(Verwachte) startdatum: 01-01-2008
Aantal proefpersonen: 12
Type: Werkelijke startdatum

Ethische beoordeling

Positief advies
Datum: 23-11-2007
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL662
NTR-old	NTR1167
Ander register	MEC : MEC 07-2-097
ISRCTN	Wordt niet aangevraagd/Observational study

Resultaten

Samenvatting resultaten

N/A