Measurement of cytokines (IL-1*) after shear force application at the skin

Published: 26-03-2014
Last updated: 24-04-2024

The objective of this studie is to gather knowledge about cytokine concentrations (IL-1 *) in the skin of healthy volunteers after the application of shear- force. We want to use this knowledge in the future to investigate if different prophylactic...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON40377

Source
ToetsingOnline

Brief title
Measurement of cytokines (IL-1*) after shear force application at the skin

Condition

- Skin and subcutaneous tissue disorders NEC

Synonym
bedsores, Pressure ulcers

Research involving
Human

Sponsors and support

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

Intervention

Keyword: IL-1, Sebutape, Shear- force, Skin

Outcome measures

Primary outcome

IL-1 * concentration (pg/ml)

Secondary outcome

Bloodflow

Erythema index

Study description

Background summary

A pressure ulcer is localized tissue injury to the superficial layer of the skin and/ or the underlying tissue. Pressure ulcers are most likely to develop in skin areas exposed to pressure, shear and friction. Shear- force is an important contributing factor and wound dressing are possibly capable to reduce shear force at the skin. At this moment there's nog good marker to detect the effect of shear- force at the skin. A potential marker could be cytokines (IL-1*) which are released after mechanical loading of the skin. A previous studie have shown a significant increased level of IL-1* after the application of pressure. We want to investigate if these cytokines are significant increased after the application of shear- force at the skin.

Study objective

The objective of this studie is to gather knowledge about cytokine concentrations (IL-1 *) in the skin of healthy volunteers after the application of shear- force. We want to use this knowledge in the future to investigate if different prophylactic wound dressings are capable to reduce shear force at the skin. This could be interesting in the prevention of pressure ulcers.

Study design

With the use of a special developed shear- force model are we going to administer 19 Newton (2 kg) shear at the palmar side of the under arm in 10 healthy volunteers. As a control we ware going to put the shear- force model at

the other arm without the application of shear- force. Before the use of the shear- force model we will mark an area of 2,5 cm by 3 cm in the centre where the shear pad is going to be placed and perform cytokine measurements with the use of Sebutape in this area. Sebutape is capable to absorp cytokines from the skin. After that we will measure the bloodflow with lasserdoppler (MoorLDI2) and the erythema index with the use of a colorimeter (DSMII Colormeter). After the use of the shear force- model we will perform cytokine, bloodflow and erythema index measurements again.
At another research day, we follow the same procedure but this time we are going to apply 15 minutes shear and 15 minutes pressure instead of 30 minutes. Then we will extract the cytokines from the Sebutape with the use of ELISA.

Study burden and risks

There's no risk involved for the healthy volunteers, because the shear- force in normal life can range between 0- 100 N. We will only administer 19 N which is much lower. We will work with healthy volunteers with a low risk on the development of pressure ulcers.

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

Healthy volunteers (male)
Age 20- 30 years
BMI 20- 30
Braden score > 20

Exclusion criteria

Injury lower arms
Skin diseases (psoriasis, eczema)
Not able to give informed consent
Malignicy
Muscle disorders

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):	03-11-2014
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	26-03-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-08-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-10-2014
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	NL46877.068.13
Other	volgt nog via clinicaltrials.gov

Study results

Date completed:	28-11-2014
Actual enrolment:	10