Measurement of cytokines, bloodflow and erythema after shear- force application of the skin in patients with Diabetes Mellitus

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1. The objective of this study is to aquire knowledge about the development of reactive hyperaemia and inflammatory responses of the skin after shear- force and pressure loading. We want to investigate if patients with diabetes type 2 will develop...

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

Summary

ID

NL-OMON42149

Source
ToetsingOnline

Brief title
The effect of shear- force in patients with Diabetes Mellitus

Condition

- Diabetic complications
- Peripheral neuropathies
- Skin and subcutaneous tissue disorders NEC

Synonym
pressure sores, Pressure ulcer

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: Charcot ostheorarthropathy, Cytokines, Pressue ulcers, Shear- force

Outcome measures

Primary outcome

1. IL-1 */ totale protein ratio

2. Bloodflow of the skin (in flux)

3. Erythema index of the skin

4. Cutaneous microbiome

Secondary outcome

not applicable

Study description

Background summary

1. Pressure ulcers, also known as bedsores occurs as a result of mechanical loading (combination of pressure and shear- force) of the skin. We proved that IL-1alpha (measurement of skin damage) and reactive hyperaemia (RH) are increased after a combined loading of pressure and shear- force with our own developed shear- force model. This RH is propably a protective mechanism of the loaded skin and is clinically seen as blanchable erythema. Blanchable erythema is seen as an important risk indicator for the development of pressure ulcers. Patients with Diabetes Mellitus type 2, however, will develop less blanchable erythema (RH), because of a decreased micro vascular function. Therefore, they will get less preventive measures against pressure ulcers. We do expect, however, that more skin damage occurs when RH is decreased, so we want to investigate if patients with type 2 diabetes (with or without neuropathy) will develop less RH and more skin damage (IL-1alpha) after shear force application at the skin compared with healthy volunteers.

2. Charcot- neuro- ostheoarthropathy is a rare, but serious complication of polyneuropathy. Most of the times it occurs at the feet in patients with diabetes with neuropathy. It is associated with inflammation, hyperaemia, bone deformation and luxation of the joints. The pathogenesis is not well understood: the hypermic response of the skin to external stimuli is increased, but we do not know if this hyperaemia is a result of primary hypervascularity or a increase in primary cytokines. Our research model gives us the opportunity to investigate if: the local cytokine production is increased in patients with diabetes type with neuropathy and a history of charcot ostheoarthropathy after shear- force application at the skin compared with patients with type 2 diabetes with neuropathy.

Study objective

1. The objective of this study is to aquire knowledge about the development of reactive hyperaemia and inflammatory responses of the skin after shear- force and pressure loading. We want to investigate if patients with diabetes type 2 will develop more skin damage, because of a decreased microvascular function.

2. The second objective of this study is: to investigate if the cytokine production of the skin is increased in patients with type 2 diabetes with a history of Charcot ostheoarthropathy in comparison with patients with neuropathy without a history of Charcot ostheoarthropathy.

3. The third objective is to investigate the differences in cutaneous microbiome between the different groups. We also want to investigate if the cutaneous microbiome changes after the application of pressure and shear

Study design

First we draw at which arm we are going to apply pressure and shear- force and at which arm we are going to apply pressure only.
The participant is asked to put arms on a support cushion. Then we mark an area of 2.5 cm x 3 cm with a permanent marker at the plantar aspect of both fore-arms and the adhesive side of a Sebutape is placed within this area for collection of IL-1*/ total protein concentrations in a non- loaded situation (event 1) for two minutes. Second, we measure the microbiome by taking a skin swab. Third we measure the cutaneous blood cell flux within the borders of the marked area with a Laser doppler. Finally, we measure the erythema index in this area with a colorimeter. Then we place the shear- pad over the marked area we apply 9,8 Newton (N) pressure with 19 N shear- force for half an hour. After this period a new swab is taken from the skin and a Sebutape is placed for two minutes, followed by cutaneous blood cell flux and the erythema index measurement within the borders of the marked area. We repeat these measures (excpet for the skin swab) after 5, 10, 15, 20, 60 minutes

At the same time we performed the same experiment at thethe other arm, but instead of loading this arm with shear- force and pressure, we apply only 9,8 N pressure at this arm. The same measures with the skin swab, sebutape, laser dopler and colorimeter are done before and after loading of the skin. The measures are repeated at 5, 10, 15, 20, 60 minutes.

Study burden and risks

Very low risk, this shear- force model was shown to be safe in healhty volunteers. The shear- force range in normal life is between 0 -100Newton. We will only administer 19 Newton shear-force which is much lower. The invasiveness of this study is the 3 hours duration of the experiment.

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

Group A:
- Healthy volunteers
- age 40 years or older and 75 years and younger;Group B;
- patients with Diabetes Mellitus type 2 (DM) without neuropathy
- age 40 years or older and 75 years and younger
- Valk score < 4;Group C:
- Patients with DM type 2 with neuropathy
- age 40 years or older and 75 years and younger
- Valk score > 4;Group D
- Patients with (pre)- existing Charcot Ostheoarhtropathy
- age 40 years or older and 75 years and younger
- Valk score > 4;In all patients we are going to determine the Valk score to measure the amount of neuropathy in patients. The Valk score is going to be determined by someone of the research committee, or under the supervision of someone of the research committee.

Exclusion criteria

- Trauma fore arms
- Skin diseases (psoriasis, eczema)
- NSAID use in last seven days
- Corticosteroïds
- Auto- iimune diseases
- Muscular dystrophy
- Malignancy
- Participant is unable to give informed consent
- No peripheral pulsations (a. radialis, a. dorsalis pedis, a. tibialis anterior)
- Hab1c percentage last 3 months > 11%

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2015
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	11-02-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-04-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-06-2015
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	NL50794.068.14
Other	Voorlopig nog niet goedgekeurd