

Investigation into the effect of pressure and shear on tissue viability of human skin.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Skin vascular abnormalities
Study type	Interventional

Summary

ID

NL-OMON43741

Source

ToetsingOnline

Brief title

Effect of pressure and shear on skin vitality.

Condition

- Skin vascular abnormalities

Synonym

decubitus, pressure ulcers

Research involving

Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh

Source(s) of monetary or material Support: STW

Intervention

Keyword: blood flow, pressure, shear, skin

Outcome measures

Primary outcome

Oxygensaturation and blood flow, during and after load application. The change in these parameters for different combinations of pressure and shear.

Secondary outcome

Tissue thickness (muscle, subcutaneous fat and skin), group effects.

Study description

Background summary

Pressure ulcers are a significant problem in healthcare, not only affecting the quality of life, morbidity and mortality of patients but also in terms of healthcare costs. The prevalence of pressure ulcers in healthcare institutions in the Netherlands was on average 8.3% (range 0% - 24%) in 2012. These figures are comparable with other Western countries such as UK, Canada and the USA . Most pressure ulcers in healthcare institutions in the Netherlands heal within three months, but in the home care situation almost 50% of the pressure ulcers do not heal within six months. The costs associated with pressure ulcers in the Netherlands alone is over 200 million Euros annually.

Although the exact aetiology of pressure ulcers is still under debate, there is consensus that pressure ulcers develop when tissue is devitalized. Tissue viability depends on the microcirculation for the exchange of oxygen, carbon dioxide, nutrients, water and waste products. If the microcirculation is blocked, waste products accumulate and an oxygen deficiency arises, leading to deterioration of the cells and the tissues. A few factors are directly linked to the development of pressure ulcers: immobility, mechanical loading (pressure and/or shear), moisture and ischemia. Immobility is seen as a prerequisite for the development of a pressure ulcer, and also has an effect on the mechanical load exerted on the tissue.

If loading is persistent for a longer period of time, tissue damage can occur as a direct result of internal stresses or as an indirect results of changed blood circulation.

To improve prevention of pressures ulcers, more knowledge is needed on the relation between loading on the skin and the change in blood circulation. In

particular, the effect of shear on the skin microcirculation is unknown. Within this research we want to investigate the relation between pressure and/or shear and the change in circulation and whether this response changed with age of patient groups.

Study objective

This study will investigate the effect of shear and pressure on tissue viability of human skin. Skin vitality is determined by tissue oxygenation and blood flow, measured with the 'Oxygen to See'. The focus will be on individual response patterns and possibly identification of groups of response patterns. The aim of this study is to gather new knowledge on the effect of shear and thereby help in quantifying the risk for development of pressure ulcers.

Study design

Experimental, non-randomised intervention study. The intervention is systematic application of pressure and shear forces on the skin.

Intervention

Application of eight different randomised (block randomisation) pressure and shear combinations on the sacrum. Each condition start with a one minute baseline (no load), followed by application of the load during 5 minutes and after load removal the reaction will be measured for 7.5 minutes.

Study burden and risks

Participants will be asked to come to the laboratory and lie still for 1 or 2 hours consecutive (in total 2 hours). The application of pressure and shear forces could potentially lead to skin damage. The range of forces stays well within the range of normal sitting and lying and is well within range of comparable studies. Also the loading time of 5 minutes is within range of normal sitting duration. Therefore we expect the risk for skin damage to be low. There are no direct benefits for subjects participating in this study.

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 participants

- Age between 18 and 35 years OR 60 years or older
- Considered to be healthy
- Caucasian/ white skin color; Spinal Cord Injured patients
- Minimal 1 year after lesion
- Complete spinal cord injury
- Wheelchair bound in daily life
- Caucasian/ white skin color

Exclusion criteria

Healthy participants

- Skin colour deviations at site of measurement
- Surgery at the area of measurement
- Pregnancy
- Unable of lying still for 2 hours
- History of pressure ulcers or other circulation diseases (e.g. diabetes); Spinal Cord Injured patients
- Skin colour deviations at site of measurement
- Surgery at the area of measurement

- Pregnancy
- Unable of lying still for 1 hour
- A pressure ulcer category 2 or higher in the past year

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Will not start

Enrollment: 30

Type: Actual

Ethics review

Approved WMO

Date: 23-06-2015

Application type: First submission

Review commission: METC Twente (Enschede)

Approved WMO

Date: 16-09-2016

Application type: Amendment

Review commission: METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25894

Source: NTR

Title:

In other registers

Register	ID
CCMO	NL53767.044.15
OMON	NL-OMON25894