Biomarkers for soft tissue damage in a rigid and a soft-layered spineboard

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON40891

Source
ToetsingOnline

Brief title
Biomarkers spineboard

Condition

- Tissue disorders NEC
- Injuries NEC
- Skin and subcutaneous tissue therapeutic procedures

Synonym
cytokine production, skin reaction to pressure

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: Biomarkers, Soft-tissue damage, Spineboard, Tissue-interface pressure

Outcome measures

Primary outcome

Cytokine and mFABp production

Secondary outcome

Tissue-interface pressures as measured by a pressure mapping mat

Redness of the skin

Xomfort of lying on the spineboard.

Study description

Background summary

Accident victims who are at risk for spinal column injury are transported to the hospital on a rigid spineboard, as indicated in protocols. Patient transport on a rigid spineboard has inherent risks: because of the rigid surface, there is a chance of developing pressure ulcers, especially when the patient lies on the rigid spineboard for a prolonged time. Furthermore, the lack of comfort due to lying on a rigid surface may cause unrest in the patient, leading to shifting to find a more comfortable position. When the patient has an unstable fracture of the spine, the shifting may lead to worsening of the injury. In the worst case, this may lead to paralysis due to (further) damage of the spinal cord by the moving fracture parts. It is therefore of utmost importance to be able to offer the patient an alternative, which accommodates the objections of discomfort and the risk of pressure ulcer development.

Study objective

In this study we want to investigate if there are differences in cytokine and mFABp production when using a rigid and a soft-layered spineboard, in relation to tissue-interface pressures. Furthermore, redness of the skin and experienced comfort are documented.

Study design

Prospective, randomized intervention study

Intervention

Subjects lie on both spineboards for a period of three times twenty minutes. Photographs are made of the skin of the back/buttocks. Every twenty minutes sebutapes are (re)placed on in advance marked places of the skin.
Tissue-interface pressures are registered continuously using a pressure mapping mat which is placed on top of the spineboard. Comfort is scored using a visual analog scale.

Study burden and risks

The burden of this study consists of a time investment of two time three hours. In this time, the skin of the back and buttocks are judged on redness multiple times and photographs are taken of this area. Subjects lie on the spineboard for a total of one hour during both sessions. For the remainder of the time they are not allowed to lie on their back en sit down (standing up and lieing on the side or prone is allowed) During the entire session sebutapes are (re)placed on in advance marked out places of the body. This is a non-invasive, painfree procedure.
Subjects are at minimal risk to develop non-blanchable erythema (grade 1 pressure ulcer) of the skin. This risk however is very small due to the limited time the subjects spends on the spineboard. Furthermore, in an earlier study (NL 18313.068.07) patients have been lying on the rigid spineboard for a maximum of two hours. None of the participants developed non-blanchable nedness (grade 1 pressure ulcer).

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

Caucasian males
Age 20-30 years
Body Mass Index (BMI) 19-25

Exclusion criteria

History of pressure ulcers
Skin conditions such as eczema, rashes, psoriasis with local expression on the buttocks/sacrum.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-09-2015
Enrollment:	14
Type:	Actual

Medical products/devices used

Generic name:	rigid spineboard; soft-layered spineboard
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-08-2014
Application type:	First submission
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	NL49146.068.14