Indicators for skin damage comparing two types of spineboard.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27531

Source
NTR

Brief title
Biomarkers spineboard

Health condition

Pressure ulcer
Tissue-interface pressure
Comfort
Drukplekken
Weefsel-oppervlakte druk
Comfort

Sponsors and support

Primary sponsor: University Medical Center Maastricht
Source(s) of monetary or material Support: University Medical Center Maastricht

Intervention

Outcome measures

Primary outcome

Tissue-interface pressures as measured by a pressure mapping mat; redness of the skin; comfort of the spineboard.

Secondary outcome

Tissue-interface pressures as measured by a pressure mapping mat; redness of the skin; comfort of the spineboard.

Study description

Background summary

Background of the study: 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.

Objective of the study: In this study we want to investigate if there are differences in cytokine 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

Study population: Caucasian males ages between 20 and 30 years of age, who have never had pressure ulcers en do not have skin problems at the time of the study.

Intervention: Subjects ly 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.

Primary study parameters/outcome of the study: cytokine production

Secundary study parameters/outcome of the study (if applicable): Tissue-interface pressures as measured by a pressure mapping mat; redness of the skin; comfort of the spineboard.

Study objective

Cytokine production differs when subjects ly on the rigid spineboard compared to the soft-layered spineboard.

Study design

1 hour, 2 hours

Intervention

Subjects ly 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.

Contacts

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Eligibility criteria

Inclusion criteria

- Caucasian males

- Age 20-30 years

Exclusion criteria

- History of pressure ulcers

- Skin conditions

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2014
Enrollment:	10
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL4317
NTR-old	NTR4537
Other	: ABR nummer 49146

Study results