Evaluation of a newly developed spineboard in anaesthetized patients.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Injuries NEC
Study type	Interventional

Summary

ID

NL-OMON37263

Source
ToetsingOnline

Brief title
Spineboard

Condition

- Injuries NEC
- Skin and subcutaneous tissue disorders NEC

Synonym
decubitus, pressure ulcers

Research involving
Human

Sponsors and support

Primary sponsor: Traumacentrum Limburg / RVE MIC
Source(s) of monetary or material Support: Ministerie van OC&W,Technovas BV

Intervention

Keyword: Anaesthesia, Comfort, Pressure mapping, Spineboard

Outcome measures

Primary outcome

Pressure on the body such as measured with a pressure measuring device.

Secondary outcome

Redness of the skin, experienced comfort of the material the patient had been

lying on.

Study description

Background summary

Transportation of trauma patients on a spineboard is associated with certain risks: because of the hard surface of the currently used spineboard patients are at risk for developing pressure ulcers, especially when they lie on the surface for prolonged periods of time. Furthermore, the discomfort of lying on a hard surface may cause the patient trying to move around in order to find a more comfortable position. If the patient has an unstable vertebral fracture, this may result in the unfavourable situation where the injury becomes more serious due to movements of the patient. The worst case scenario would be that movement of the unstable fracture causes damage to the spinal cord, thereby leaving the patient paralysed. It is therefore of the utmost importance that research is done to find alternatives for this spineboard. This study is aimed at evaluating such an alternative.

Study objective

We want to study whether there is a difference with respect to the pressure exerted onto the body when using a normal spineboard and a newly developed spineboard, related to the level of consciousness of the volunteer. Also the experienced comfort for lying on the normal spineboard and lying on the newly developed spineboard will be evaluated.

Study design

Prospective randomised multicenter intervention study.

Intervention

Patients are randomly assigned to one of the two study groups. Participating patients are lifted onto one of the two spineboard after they have received their anaesthetics.

Study burden and risks

The burden of this study comprises a time investment of 15 minutes used for explaining the nature of the study and the answering of a limited number of questions after the surgery.
The volunteers are at limited risk of developing non-blanchable redness of the skin (decubitus 1st grade). This risk is very small since the time spent on the spineboard will be limited.

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

surgery under general anaesthetics

Exclusion criteria

decubitus in medical history

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-02-2008
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Spineboard
Registration:	No

Ethics review

Approved WMO Date:	09-08-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-08-2011
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	NL18313.068.07