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Effects of unconsciousness during spinal immobilization on tissue-interface pressures

Submission date
10/04/2014

Recruitment status
No longer recruiting

Registration date
24/04/2014

Overall study status
Completed

Last Edited
24/04/2014

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Victims of a serious accident such as an car crash are often transported to the hospital on a rigid spineboard. A spineboard is a rigid device designed to protect the spine when spinal injury is suspected. Because it is very uncomfortable and even painful to lie on a rigid spineboard, we developed a softer type of spineboard. It is important to know if the spine and other body parts are sufficiently supported by the device. One way to test this is by looking at the contact the body makes with the device by using a pressure mapping mat. We have already done this in healthy, awake volunteers. Now we want to test the support in anaesthetised patients to see how the device would support an unconscious or paralyzed patient. Because lying on a device may also influence blood supply to the skin, we also look at the skin at the back of the patient.

Who can participate?
Men and women aged 18 or older undergoing abdominal wall herniation repair under general anaesthetic at our Day Surgery facility.

What does the study involve?
If you decide to participate in this study, before the surgery you will be asked to describe any pain (other than that related to the abdominal wall herniation) on a scale of 0 (no pain) to 10 (worst imaginable pain). Also, your back will be assessed for any redness and a photo will be taken of your back. After you are put under general anaesthetic, you will be randomly allocated to be placed on one of the two spineboards being investigated. The spineboard is equipped with a special pressure mapping mat, which continuously registers the pressure between the body and the spineboard. After the surgery, when you are transferred from the spineboard to a bed from the recovery department, you will be rolled onto your side and your back will be judged for redness and a photo will be taken. Two hours after the end of the surgery, when the anaesthetic has worn off, you will be asked to describe any pain and your back will be assessed for any redness. Awake healthy volunteers will also be placed on each spineboard for 15 minutes, with an interval between the devices of 5 minutes, while pressures are recorded continuously.

What are the possible benefits and risks of participating?
There are no benefits for the patients participating in this study but future victims of a serious accident may benefit from the results obtained in this study. The risks are the development of passing redness of the back and passing pain in the back.

Where is the study run from?
The study is run from the Maastricht University Medical Center in Maastricht, Netherlands.

When is the study starting and how long is it expected to run for?
The study ran from February 2008 to February 2010.

Who is funding the study?
Maastricht University Medical Center (Netherlands).

Who is the main contact?
Prof Peter Brink
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
ToetsingOnline NL 18313.068.0

Study information

Scientific Title
Effects of unconsciousness during spinal immobilization on tissue-interface pressures: a randomized controlled trial comparing a standard rigid spineboard with a newly developed soft-layered long spineboard

Study objectives
This study investigates the hypothesis that when lying on a rigid spineboard, unconsciousness results in higher tissue-interface pressure compared to the awake status. Our second hypothesis is that there is no difference in tissue-interface pressure between anaesthetized and awake status when lying on the soft-layered long spineboard.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Research Ethics Committee of the Maastricht University Medical Center, ref. MEC 07-2-050

Primary study design
Interventional

Study design
Single-center prospective randomized single-blinded comparative study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Spinal immobilization in unconscious patients

Interventions
Two different support devices designed for prehospital trauma care are tested: a standard long spineboard (Ferno-Washington, Wilmington, OH), and a prototype soft-layered long spineboard (Technovas, Meerssen, The Netherlands). After induction of anesthesia, patients are randomly assigned to one of the two devices. The pressure-mapping mat is placed on the device and the patient is then placed on the device. Pressure is recorded during the entire surgery. Before, directly after and 2 hours after surgery the back is visually inspected for redness. Before and 2 hours after surgery the patient is asked to judge pain on a VAS scale with 0=no pain and 10=worst possible pain. The control group consists of awake healthy volunteers who are randomly put on each device for 15 minutes, with an interval between the devices of 5 minutes, while tissue-interface pressures are recorded continuously.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Tissue-interface pressures in mmHg, as measured by an Xsensor 9612 pressure mapping mat. Tissue-interface pressures are measured continuously for the whole time the patient lies on the device. Analyses are done on average tissue-interface pressures during the first minute, 15th minute and last minute of the measurement.

Key secondary outcome(s)
1. Redness of the back. This is visually judged prior to surgery, when the patient is in the waiting room of the Day Surgery facility; and directly after surgery when the patient is transferred from the device to the recovery bed. At both time points a photo is taken for judgement by the second judge.
2. Pain is assessed when the patient is in the waiting room of the Day Surgery facility, and 2 hours after surgery, using a 10-point VAS with 0=no pain and 10=worst pain imaginable.

Specifically the patient is asked to judge pain on the scapulae, upper back, lower back, buttocks and heels. The patient is asked to disregard any pain from the abdominal wall herniation or from the surgery.

Completion date
15/02/2010

Eligibility

Key inclusion criteria
1. Age 18 or older
2. Enlisted for abdominal wall herniation repair under general aneasthetics at our Day Surgery facility
3. Expected surgery duration of less than two hours

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
History of pressure ulcers, pain other than related to the abdominal wall herniation

Date of first enrolment
15/02/2008

Date of final enrolment
15/02/2010

Locations

Countries of recruitment
Netherlands

Study participating centre

P. Debyelaan 25
Maastricht
Netherlands
6229HX

Sponsor information

Organisation
Maastricht University Medical Center (Netherlands)

ROR
https://ror.org/02d9ce178

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Maastricht University Medical Center (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration