The risk of pressure soars after use of pelvic circumferential devices

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Observational non invasive

Summary

ID

NL-OMON31121

Source
ToetsingOnline

Brief title
The risk of pressure soars after use of pelvic circumferential devices

Condition

- Fractures

Synonym
pelvic fracture

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting Nuts Ohra

Intervention

Keyword: circumferential compression device, pelvic fracture, pressure soar

Outcome measures

Primary outcome

Skin pressure (mmHg)

Secondary outcome

N.A.

Study description

Background summary

Pelvic fractures should be considered as potentially life-threatening fractures. The mortility risk enhances with increasing severity of the pelvic injury: hemodynamic unstable patients with a closed pelvic fracture have a mortality risk of approximately 27%, whereas the mortality risk is 50% for patients with an open pelvic fracture. Therefore, massive hemorrhaging leading to death is an extremely serious complication for pelvic fracures. Depending on the fracture type, this blood loss can be as high as 5 liters. Blood loss can originate from several locations, e.g., the venous and arterial plexus and bleeding fracture elements.

Fracture reduction and stabilization diminishes the potential space available for blood loss, and may tamponade massive hemorrhage. Circumferential compression of the pelvis as a means of gaining control over life-threatening hemorrhage in unstable pelvic ring injuries has been described by several authors, and is advocated by the Advanced Trauma Life Support (ATLS) Course. In the past, bed sheets were used as mean to achieve acute circumferential compression. At present, non-invasive pelvic circumferential compression devices (PCCDs) are available. The Pelvic Binder, SAM Sling en T-POD are mainly used. These may act as a temporary fix until surgical fixation interventions can be initiated.

Little scientific evidence exists for effects and risks of PCCDs. There is evidence showing that PCCD use may cause decubitus

Study objective

The aim of this study:
- To determine the amount of pressure of PCCDs on the skin. The Pelvic Binder, SAM Sling and T-POD will be compared.
- To determine the influence of body mass index on the pressure characteristics of these 3 types of PCCDs.

The results will gain insight into the risk of decubitus of PCCDs. There is a risk of tissue damage after continuous, prolonged pressure of at least 9.3 kPa (69.8 mmHg) on the skin during 2-3 hours.

Study design

To mimic the clinical situation as closely as possible, measurements will be performed in 2 settings. In the first setting, the subject is lying on a spine board, on which trauma patients are immobilized. To mimic the situation at the hospital ward, the subjects will be transferred to a hospital bed.

A Force Sensing Array (FSA) pressure mapping system will be placed around the pelvis (subjects are only allowed to wear thin clothings underneath). This pressure mat contains 16x32 pressure sensors and has been designed for determining skin pressure as readout for the risk of decubitus (dept. of Dermatology, Erasmus MC). The PCCD is positioned on top of hte FSA mat, following the protocol of the supplier. One measurement without binder will serve as control. To reduced biological variation as much as possible, a cross-over design is chosen, in which all three types of PCCDs will be tested on each subject, in a randomized order.

Preliminary measurements have revealed that a time frame of 30 minutes in between two measurements is sufficient to rule out carry over effects.

Study burden and risks

For each PCCD one measurement will be performed, taking up to 20 minutes. There will be a pause of 30 minutes in between two measurements, summing up to a total duration of the examination of approximately 2 hours.
Healthy volunteers do not carry a risk of decubitus, as decubitus only occurs if a continuous pressure of >9.3 kPa (69.8 mmHg) is put on the skin for at least 2-3 hours.

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 volunteers between 18 and 70 years of age

Exclusion criteria

Bedical history is not blank

Study design

Design

Study phase:	4
Study type:	Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-02-2008
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Pelvic Circumferential Compression Device
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	28-09-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL18718.078.07