Risk of developing pressure sores by non-invasive pelvic circumferential compression devices.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26107

Source
Nationaal Trial Register

Brief title
N/A

Health condition

pelvic fracture, circumferential compression device, pressure sores, bekkenfractuur, bekkenbinder, decubitus risico

Sponsors and support

Primary sponsor: Erasmus MC, Department of Surgery-Traumatology, Medical Ethics Committee (METC)
Source(s) of monetary or material Support: Fonds Nuts Ohra

Intervention

Outcome measures

Primary outcome

Exerted pressure (distribution) on the skin (kPa)

Secondary outcome

N/A

Study description

Background summary

The aim of our study is to measure the skin pressure (kPa) exerted by three different commercially available PCCDs in 80 healthy volunteers. The skin pressure may represent the risk of pressure sores. Literature data indicate a relation between Body Mass Index (BMI) and decubitus risk. Therefore, a wide range of BMI will be represented in this study. The aim is to include 25-30 subjects in each of the following BMI-groups: (1) underweight, BMI<18.5; (2) normal weight, BMI 18.5-24.9; (3) overweight, BMI 25.0-29.9. A study poster has been designed to recruit volunteers.
While lying on a spine board, a Force Sensing Array (FSA) (Vista Medical, Winnipeg, Canada) pressure mapping system will be placed around the pelvis. Only underwear will be allowed. This mapping system has been especially developed for the purpose of investigating pressure exerted on the skin. In random order, the PCCDs will be applied, strictly following the protocol of the suppliers. After 5 minutes, subjects will be transferred to a hospital bed to mimic the clinical situation. Measurements will be continued for another 5 minutes. To minimize biological variation a cross-over design was chosen, applying all three PCCDs to all volunteers in a randomized order. Preliminary data indicate that carry-over effects can be excluded if there is 30 minutes between two measurements.

Study objective

The exerted pressure on the skin by non-invasive pelvic circumferential compression devices (PCCDs) carries a risk of pressure sores and skin necrosis in case of prolonged use. A persons Body Mass Index (BMI) is of influence on this risk.

Study design

T=0: reference

T=1: spine board, 0 minutes

T=2: spine board, 5 minutes

T=3: hospital bed, 0 minutes

T=4: hospital bed, 5 minutes

Intervention

A Force Sensing Array (FSA) pressure mapping system will be placed around the pelvis. The PCCD is positioned on top of the FSA mat, following the protocol of the supplier. Measurements will be performed in 2 settings: lying on a spine board (5 minutes) and on a hospital bed (5 minutes). All three commercialley available binders will be tested once on each subject in a cross-over design. A time frame of 30 minutes in between two measurements is sufficient to rule out carry over effects.

Contacts

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Eligibility criteria

Inclusion criteria

1. Volunteers between 18 and 70 years of age;

2. Blank medical history;

3. Signed informed consent.

Exclusion criteria

1. (History of) pelvic or low-back complaints;

2. Pelvic fractures;

3. Skin problems in the pelvic region;

4. Pregnancy

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

Ethics review

Positive opinion

Date:	13-03-2008
Application type:	First submission

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	NL1169
NTR-old	NTR1214
Other	METC Erasmus MC : MEC-2007-278
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
Knops SP, Van Lieshout EMM, Spanjersberg WR, Patka P, Schipper IB. Randomised clinical trial comparing pressure characteristics of pelvic circumferential compression devices in healthy volunteers. Injury 2011;42(10):1020-1026.