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

Gepubliceerd: 13-03-2008 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26107

Bron
NTR

Verkorte titel
N/A

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus MC, Department of Surgery-Traumatology, Medical Ethics Committee (METC)
Overige ondersteuning: Fonds Nuts Ohra

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Exerted pressure (distribution) on the skin (kPa)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

P.O. Box 2040
S.P. Knops
Researcher dept. of Surgery-Traumatology
(Room H-974)
's-Gravendijkwal 230, 3015 CE Rotterdam
Rotterdam 3000 CA
The Netherlands
+31-10 70 32419

Wetenschappelijk

P.O. Box 2040
S.P. Knops
Researcher dept. of Surgery-Traumatology
(Room H-974)
's-Gravendijkwal 230, 3015 CE Rotterdam
Rotterdam 3000 CA
The Netherlands
+31-10 70 32419

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Volunteers between 18 and 70 years of age;

2. Blank medical history;

3. Signed informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

2. Pelvic fractures;

3. Skin problems in the pelvic region;

4. Pregnancy

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	08-02-2008
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	13-03-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1169
NTR-old	NTR1214
Ander register	METC Erasmus MC : MEC-2007-278
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

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.