Temperature during orthopedic surgery.

Gepubliceerd: 10-12-2007 Laatst bijgewerkt: 13-12-2022

Obtain transient temperature data of the skin, core and wound surface during orthopedic back surgery in order to validate the numerical model of Severens for this type of surgery.

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

Samenvatting

ID

NL-OMON20910

Bron
Nationaal Trial Register

Verkorte titel
Temperature during orthopedic surgery

Aandoening

Orthopedic surgery
(NLD: Orthopedische operatie).

Ondersteuning

Primaire sponsor: Technische Universiteit Eindhoven
Den Dolech 2
5600 MB Eindhoven
Overige ondersteuning: Technische Universiteit Eindhoven
Den Dolech 2
5600 MB Eindhoven

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. 14 skin temperatures;
2. rectal temperature;
3. wound surface temperature.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective:

Obtain transient temperature data of the skin, core and wound surface during orthopedic back surgery in order to validate the numerical model of Severens etal [7] for this type of surgery.

Study design:

Observational study in which skin temperature is continuously measured with 14 wire-less thermistors and wound surface temperature is measured with an infrared camera 4 times per hour. Rectal temperature data is also stored in the study.

Main study parameters:

14 skin temperatures, rectal temperature and wound surface temperature during orthopedic surgery. Afterwards the predictions of the computer model that was developed at the Technical University Eindhoven will be compared to the obtained measurement results.
Nature and extent of the burden and risks associated with participation,
bene¯t and group relatedness
No risks are involved during the study. The burden of the study is low. Because we are interested in surgeries with larger incisions and with no other complicated interventions, patients who undergo orthopedic surgery are chosen.

Doel van het onderzoek

Obtain transient temperature data of the skin, core and wound surface during orthopedic back surgery in order to validate the numerical model of Severens for this type of surgery.

Onderzoeksopzet

1. November 2007 Writing and submitting METC application;

2. January 2008 - March 2008 Recruiting patients and perform measurements;

3. April 2008 Data analysis;

4. May 2008 & Final report.

Onderzoeksproduct en/of interventie

8 patients will be asked to participate in this study. The following measurements take place:

1. Determination of body characteristics: height, weight and fat percentage at the evening before the surgery. ALso hip and wast circumference will be measured;

2. 14 skin temperature sensors will be attached with tape to the skin, during surgery;

3. Four times per hour pictures will be taken from the wound surface with the help of an infrared camera. The surgery will not be disturbed or delayed by this;

4. Core temperature data (this parameter is measured standard) will be stored. No extra manoeuvre is needed for that. Normally, the data is destroyed after surgery, but now it will be stored;

5. All sensors are removed at the end of the surgery.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. BMI<=30 kg/m^2;

2. age 18-70;

3. patient undergoing orthopedic back surgery;

4. Caucasian.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. BMI>30 kg/m^2;

2. age <18 or >70;

3. Diabetes Mellitus;

4. Cardiovascular diseases;

5. Non-Caucasian.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2008
Aantal proefpersonen:	8
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-12-2007
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	NL1143
NTR-old	NTR1185
Ander register	: MEC 07-3-097
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

Severens N M W, Van Marken Lichtenbelt W D, Frijns A J H, Van Steenhoven A A , De Mol B A J M and Sessler D I 2007 A model to predict patient temperature during cardiac surgery Phys. Med. Biol. 52 (17) 5131-5145