Temperature during orthopedic surgery.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20910

Source
Nationaal Trial Register

Brief title
Temperature during orthopedic surgery

Health condition

Orthopedic surgery
(NLD: Orthopedische operatie).

Sponsors and support

Primary sponsor: Technische Universiteit Eindhoven
Den Dolech 2
5600 MB Eindhoven
Source(s) of monetary or material Support: Technische Universiteit Eindhoven
Den Dolech 2
5600 MB Eindhoven

Intervention

Outcome measures

Primary outcome

1. 14 skin temperatures;

2. rectal temperature;

3. wound surface temperature.

Secondary outcome

Afterwards, the measured temperatures will be compared to the prediction of the computer model developed at the Technical University of Eindhoven.

Study description

Background summary

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.

Study 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 for this type of surgery.

Study design

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.

Intervention

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.

Contacts

Public
Universiteitssingel 50, k. 2.312
Wouter Marken Lichtenbelt, van
P.O. Box 616
Maastricht 6200 MD
The Netherlands
+31 (0)43 3881629
Scientific
Universiteitssingel 50, k. 2.312
Wouter Marken Lichtenbelt, van
P.O. Box 616

Maastricht 6200 MD
The Netherlands
+31 (0)43 3881629

Eligibility criteria

Inclusion criteria

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

2. age 18-70;

3. patient undergoing orthopedic back surgery;

4. Caucasian.

Exclusion criteria

1. BMI>30 kg/m^2;

2. age <18 or >70;

3. Diabetes Mellitus;

4. Cardiovascular diseases;

5. Non-Caucasian.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2008
Enrollment:	8
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-12-2007
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	NL1143
NTR-old	NTR1185
Other	: MEC 07-3-097
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

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