The effect of prewarming on hypothermia during orthopaedic surgery and related postoperative complications.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON34711

Source
ToetsingOnline

Brief title
The effect of prewarming on perioperative hypothermia

Condition

- Other condition
- Therapeutic procedures and supportive care NEC

Synonym
Thermoregulation and cooling

Health condition

Prevention for perioperative hypothermia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Complications, Core temperature, Perioperative hypothermia, Prewarming

Outcome measures

Primary outcome

1) The occurence and time to hypothermia. Core body temperature registration

prior to, during and post surgery

2) Skin temperature prior to, during and post surgery (temperature sensor)

3) Amount of blood loss peri-operative (including Hb and Ht)

4) Established Infection

5) Thermal Comfort

6) Interventions related to shivering (such as use of pethidine)

5) Length of hospitalization stay

Secondary outcome

NA

Study description

Background summary

Perioperative hypothermia, defined as a core body temperature below 36°C is a common problem in patients undergoing surgery. It is estimated that 50 to 90% of surgical patients experience hypothermia during surgery. Hypothermia results in higher morbidity and mortality, in longer hospital stay and in decreased patient satisfaction. It has been indicated that 80% of the observed reduction in core body temperature during the first hour of general anesthesia is caused by blood redistribution; mixing the *low temperature* peripheral blood with the

high temperature core blood. The impact of this *redistribution hypothermia* may be attenuated by *pre-warming* of the low temperature peripheral blood, thereby decreasing the temperature gradient between core and periphery.
A promising and non invasive tool to monitor core body temperature during surgery is a portable telemetric system using a temperature pill swallowed by the patient. This advanced technologically to measure body temperature continuously and the use of a novel pre-warming clinical intervention in surgical patients will enable us to provide essential physiological and clinical information in the prevention of perioperative hypothermia.

Study objective

In this present study we will assess the effect of a pre-warming intervention before surgery, in order to decrease the temperature gradient from core to periphery and thereby minimize redistribution hypothermia under anesthesia, on (I) the occurrence of perioperative hypothermia (II) the incidence of postoperative complications and the length of stay in the hospital after surgery.

Study design

This study is a randomized intervention study in which the subjects will be randomly assigned to one of the 2 groups, i.e. a standard care + pre-warming intervention or standard care alone.
All participants will ingest the temperature pill at least 12 hours before surgery (4 hours to ensure passage through the stomach and 8 hours to measure temperature before surgery) which records the temperature for up to 48 hours. Skin temperature will be measured for a total of 24 hours, starting 8 hours before surgery at distinct locations (calf, upper leg, upper arm, lower arm, chest, fore head). 2 hours prior to the start of the surgery, the pre-warming intervention will be applied with the Bair Paws® system, allowing patients to adjust the temperature of the air flowing through the gown to a level that feels right for them

Intervention

2 hours prior to start of the surgery, a novel pre warming intervention will be applied using the Bair Paws® system, which offers active, adjustable warming capabilities in a patient gown allowing participants to adjust the temperature of the air flowing through the gown to a level that feels right for them.

Study burden and risks

The intake of the telemetry pill is non-invasive and not dangerous as it can be swallowed similarly as any medication pill. An ingestion of this pill will also cause no harm to the body and its function due to the sophisticated

elaboration of protection to its surrounding. The pill has been proved to be reliable and valid for measuring core body temperature at rest and during exercise and is now being used and registered at the *Food and Drug Administration (FDA)* for 19 years. Important advantages of this system are its non-invasive character, validity, ability to monitor temperature continuously and it can be used without noticing by the subject. From the >35,000 pills that have been distributed, no negative incidents have been reported.
The other techniques and measurements used in this study (skin temperature measurement and registration of amount of blood loss, wound infections, thermal comfort, use of interventions related to shivering, length of hospital stay) are completely non- invasive, painless and not dangerous and as such no additional burden for the patient.
Before and after surgery, a blood sample will be collected for the assessment of hemoglobin (Hb) and hematocrit (Ht), providing information about blood loss. In case of wound infections, blood values such as CRP will be measured every 24 hours. These are minimally invasive techniques with a small risk for complications. The only possible complication is a haematoma, which is induced in ~5% of all cases. To prevent complications, the blood withdrawal will be performed by an experienced professional and sufficient pressure will be provided after withdrawal of the needle.
The 2 hour pre-warming intervention allows the patients to adjust the temperature of the air flowing through the gown to a level that feels right for them. This warming system has been proven safe and effective and is approved by the FDA.
Research-based evidence identifies that the normalization of body temperature during the perioperative period significantly improves patient outcomes and patient satisfaction, and dramatically reduces the cost of complications related to perioperative hypothermia. Findings from the present study will enable us to provide essential physiological and clinical information for future advices to medical specialists in the prevention of perioperative hypothermia and its related clinical problems.

Contacts

Public
CtrtP Scientific Writing and Conulting

Geert Grooteplein Zuid 10
6525 GA Nijmegen
NL
Scientific
CtrtP Scientific Writing and Conulting

Geert Grooteplein Zuid 10

6525 GA Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Above 18 years of age
- Males and Females
- Scheduled for a major orthopaedic surgery (knee, hip, spine)
- Informed consent

Exclusion criteria

- Minor (below the age of 18) or incapacitated subjects
-History of diabetic neuropathy or endocrine disorder known to interfere with body temperature regulation.
-Vascular disease
-Body weight * 36.5 kg.
-Obstructive disease of the gastro-intestinal tract, including diverticulitis and inflammatory bowel disease or previous gastrointestinal surgery, except cholecystectomy and appendectomy
-Subjects that will undergo a MRI-scan within 2 days after ingestion of the pill (pill should not be in the body anymore)
-Cardiac pacemaker or other implanted electromedical devices

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2010
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	11-05-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL31389.091.10