Effectiveness of Forced Air Preoperative warming

Published: 31-12-2015
Last updated: 15-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Interventional

Summary

ID

NL-OMON42062

Source
ToetsingOnline

Brief title
FAP study

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Myocardial disorders
- Bone and joint therapeutic procedures

Synonym
hypothermia

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: research inkomsten Onze Lieve Vrouwe Gasthuis afdeling anesthesiologie

Intervention

Keyword: Forced Air Warming, Orthopaedic surgery, Preoperative

Outcome measures

Primary outcome

Main endpoint is hypothermia defined as a core temperature below 36 *C measured

with SpotOn non-invasive cutaneous thermometer.

Secondary outcome

The delta temperature between the peripheral temperature and core temperature

The delta temperature 15 min after induction and temperature in recovery room

The incidence of peri- and postoperative complications: Blood loss, AKI,

Mortality, Surgical site infection within 30 days PO, Acute Coronary Syndrome,

Myocardial infarction, Indication of re-admission

Length of stay on the recovery and in hospital

Patient satisfaction during stay on the recoveryward

Costs related to the surgical procedure for extended observation, re-admission,

homecare and treatment of complications, occurring within 30 days postoperative

Study description

Background summary

Patients undergoing surgery with general anesthesia or local regional anesthesia will have a decline in body temperature caused by redistribution of heath from the core compartment to the peripheral compartment. A core temperature below 36 degrees Celsius is defined as hypothermia. Perioperatieve hypothermia causes serious complications such as bloodclotting disorders, surgical site infections, cardiac morbidity and mortality. Recent literature shows evidence to prevent patients from intra- and postoperative hypothermia

and it*s resulting complications by using forced air prewarming.

Study objective

The primary objective of the study is to determine whether the use of pre-and intraoperative warming with a forced air technique leads to a reduction of the incidence of hypothermia compared to patients with only intra-operative forced air warming. Secondary objectives are the incidence of intra- and postoperative complications and cost effectiveness of implementing forced air prewarming.

Study design

Prospective randomized controlled trail. Patients will be randomized to the intervention group: 30min of prewarming with forces air technique in the preoperative holding and the control group: intra operative forced air warming (standardcare).

Intervention

Patients in the forced air warming group will be prewarmed, 20-30 minutes preoperatively, in the preoperative waiting room area, using a Bair Paws gown and Bairhugger warming unit for 30 minutes. Prewarming will be stopped if patients core temperature rizes above 37.5 degrees Celsius. Intra operative, warming with forced air technique will be continued according to our local standards . In addition, patients will be administered prewarmed intravenous fluids by using an active fluid warmer

Study burden and risks

Due to the observational nature of this study there are no side effects to be expected. The use of the SpotOn non invasive cutaneous thermometer is expected to be safe in patients under general anesthesia or spinal anesthesia. The use of forced air prewarming with Bairhugger is expected to be safe, there is no risk of burn wounds when used according to the manufacturers manual. Pre warming will be stopped if patients core temperature rises above 37,5 C.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) Patients 18 years and older
2) elective orthopedic surgery: total knee arthroplasty and total hip arthroplasty
3) Patients classified ASA I, II or III

Exclusion criteria

1) Patients younger than 18 years
2) Surgery < 60 minutes
3) Patients admitted for day care surgery
4) Patients undergoing emergent surgery
5) Other surgery than total knee- and hip arthroplasty
6) ASA IV of V

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2016
Enrollment:	222
Type:	Actual

Medical products/devices used

Generic name:	Bair Paws Gown
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	31-12-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22080
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL52209.100.15
OMON	NL-OMON22080