Effectiveness of Forced Air Preoperative warming

No registrations found.

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

Summary

ID

NL-OMON22080

Source
Nationaal Trial Register

Brief title
FAP study

Health condition

Postoperative hypothermia

Sponsors and support

Primary sponsor: OLVG Hospital (Onze Lieve Vrouwe Gasthuis), Amsterdam, the Netherlands
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

The primary endpoint of this study is the percentage of postoperative hypothermic patients with temperature below 36 degrees Celsius measured during entrance of the OR, 15 min after induction of anaesthesia and on the recovery room at first temperature.

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 PACU and in hospital

-Patient satisfaction during stay on the PACU.

-Costs related to the surgical procedure for extended observation, re-admission, homecare and treatment of complications, occurring within 30 days postoperative. To obtain these data e ill intervie patients by t
telephone 0 day's postoperative.

Study description

Background summary

Rationale: 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. Intra- and postoperative hypothermia causes serious complications such as blood clotting 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 before surgery (so called prewarming),in stead of forced air warming only during surgery (standard care)

Objective: The primary objective of the study is to determine whether the use of preoperative warming with a forced air technique leads to a reduction of the incidence of hypothermia compared to patients with standard care. 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 in the preoperative holding and the control group: standard preoperative care.

Study population: Eligible patients are patients undergoing orthopaedic surgery for total knee – and hip arthroplasty.
Intervention (if applicable): 30 minutes preoperative warming with forced air technique (FAP)

by using the ®Bair Paws gown and ®Bairhugger warming unit.

Main study parameters/endpoints: ain endpoint is hypothermia defined as a core temperature belo elsius measured with ®SpotOn non-invasive cutaneous thermometer.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Due to the observational nature of this study there are no side effects to be expected. The use of the ®SpotOn non invasive thermometer, measuring core temperature, is expected to be safe in patients under general anaesthesia or spinal anaesthesia. Measuring core temperature with ®Spot-On thermometer is a validated method, proven by literature. The use of forced air rewarming with ®Bair Paws gown and ®Bairhugger warming unit is expected to be safe.

Study objective

The use of preoperative warming of patients undergoing total hip- or knee arthroplasty with a forced air technique will reduce the incidence of postoperative hypothermia.

Study design

-30 minutes preoperative

-intraoperative

-postoperative during stay on PACU

-30 day's postoperative

Intervention

Patients in the FAP group will be prewarmed, 30 minutes preoperatively, in the preoperative waiting room, using a ®Bair Paws gown for 30 minutes. The ®Bair Paws perioperative single use patient gown (Arizant Healthcare, UK) is a gown developed for perioperative skin surface warming. The gown will be connected via corrugated hose to a ®Bair Hugger warming unit to provide intraoperative warming. The temperature output of the device is set on a temperature and 43 Celsius. Temperature output can be adjusted according to the patient needs.

Patients in the standard care group will receive 30 minutes preoperatively a disposable heated blanket in the preoperative waiting room area. Intra-operative a forced air warming with ®Bair Paws gown will be applied. The ®Bair Paws perioperative single use patient gown (Arizant Healthcare, UK) is a gown developed for perioperative skin surface warming. The gown will be connected via corrugated hose to a ®Bair Hugger warming unit to provide intraoperative warming. The temperature output of the device is set on a temperature and 43

degrees Celsius. Temperature output can be adjusted according to the patient needs. Furthermore administered iv fluids will be warmed by an active fluid warmer (enFlow®IV Fluid Warmer, Vital Signs A GE Healthcare company).

Contacts

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Eligibility criteria

Inclusion criteria

- >18y

- Patients scheduled for total knee – and total hip arthroplasty

- ASA I, II or III

Exclusion criteria

- < 18y

- Surgery < 60 minutes

- Day care surgery

- Surgical Emergency

- Other surgery than total knee – and total hip arthroplasty

- ASA IV or V

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-01-2016
Enrollment:	222
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-02-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42062
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5639
NTR-old	NTR5754
CCMO	NL52209.100.15
OMON	NL-OMON42062

Study results

Summary results
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