Effectiveness of Forced Air Preoperative warming

Gepubliceerd: 19-02-2016 Laatst bijgewerkt: 15-05-2024

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.

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

Samenvatting

ID

NL-OMON22080

Bron
Nationaal Trial Register

Verkorte titel
FAP study

Aandoening

Postoperative hypothermia

Ondersteuning

Primaire sponsor: OLVG Hospital (Onze Lieve Vrouwe Gasthuis), Amsterdam, the Netherlands
Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

-30 minutes preoperative

-intraoperative

-postoperative during stay on PACU

-30 day's postoperative

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

Onze Lieve Vrouwe Gasthuis

M.A.M. Siepel
Postbus 95500

Amsterdam 1090HM
The Netherlands

Telefoon: +31 20 5991111, sein 4777

Wetenschappelijk

Onze Lieve Vrouwe Gasthuis

M.A.M. Siepel
Postbus 95500

Amsterdam 1090HM
The Netherlands
Telefoon: +31 20 5991111, sein 4777

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- >18y

- Patients scheduled for total knee – and total hip arthroplasty

- ASA I, II or III

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- < 18y

- Surgery < 60 minutes

- Day care surgery

- Surgical Emergency

- Other surgery than total knee – and total hip arthroplasty

- ASA IV or V

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	11-01-2016
Aantal proefpersonen:	222
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-02-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42062
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

-