# Perioperative temperature management: a big small problem

Published: 08-02-2008
Last updated: 10-05-2024

Does preoperative heating of patients undergoing elective orthopedic surgery reduce the incidence of intraoperative hypothermia and postoperative comfort and modulate postoperative glucose and insulin blood levels?

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON31705

**Source**
ToetsingOnline

**Brief title**
HOT (HypOThermia)

### Condition

- Other condition
- Bone and joint therapeutic procedures

**Synonym**
Perioperative hypothermia, perioperative temperature loss

**Health condition**

Perioperatief bloedverlies en postoperatieve hyperglycemie

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Hypothermia, Prewarming, Recovery, Surgery

## Outcome measures

### Primary outcome

Incidence of perioperative hypothermia

### Secondary outcome

Perioperative blood loss

Patient discomfort as defined by pain, nausea and vomiting, shivering and

thermal discomfort

Postoperative glucose and insulin levels

# Study description

### Background summary

Hypothermia, defined as a core temperature below 36 degrees Celcius, is commonly seen in patients undergoing surgery. Intraoperative hypothermia is related to postoperative patient discomfort, impaired wound healing, increased blood loss, anxiety and disturbances in glucose and insulin levels. Prewarming of patients prior to surgery may result in maintenance of intraoperative temperature and reduce postoperative complications. We therefore aim to investigate the effects of prewarming of patients undergoing elective orthopedic surgery on intraoperative temperature control and blood loss and postoperative patient discomfort and glucose and insulin levels.

### Study objective

Does preoperative heating of patients undergoing elective orthopedic surgery reduce the incidence of intraoperative hypothermia and postoperative comfort

and modulate postoperative glucose and insulin blood levels?

### Study design

Multi-center, prospective, randomized clinical trial.

### Study burden and risks

All measurement parameters are part of standard perioperative and clinical care, except for drawing of ablood samples for the determination of glucose, insulin, Hb, Ht, creatinine kinase, lactate, APTT and INR (in total 76 ml)
There are three modalities that will be applied to draw patient blood:

1) Blood sampling from an intravenous catheter. Peripheral intravenous catheter placement is standard perioperative procedure in all surgical patients, and will therefore not add up to patient discomfort in the present study.

2) Blood sampling by intravenous puncture. There is a 10-20% chance that blood sampling can not sufficiently be performed through an intravenous catheter. In this case, blood sampling will be performed by an intravenous puncture. Blood sampling will be performed on three different time-points, two during anesthesia and one at the postoperative ward. On the postoperative ward patients are recovering from anesthesia and patient discomfort due to blood sampling will be the highest in this particular population.

3) Glucose levels using a glucose meter device. Postoperative serum glucose levels can be measured using a glucose meter device. A single puncture in the index finger the obtain blood will be necessary and this will be minimal invasive.

## 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

Patients undergoing an elective orthopedic knee- or hip replacement
Participation based on informed consent
> 18 years old and < 85 years old

## Exclusion criteria

BMI 18.5 > x < 40
Pregnancy
Non elective trauma patients
Infectious or febrile patients (> 37.5oC)
Diabetes Mellitus
Combined surgery
Anemia (Hb < 4.0 mmol/l)

# Study design

## Design

| | |
|---|---|
| Study type: | Observational invasive |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

| | |
|---|---|
| Control: | Active |
| Primary purpose: | Health services research |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 07-04-2008 |
| Enrollment: | 279 |
| Type: | Actual |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 08-02-2008 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

## 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 | NL17356.029.07 |