

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Unexpected high incidence of hypothermia before induction of anesthesia in elective surgical patients

Trial Acronym

Preop Temp

URL of the trial

[---]*

Brief Summary in Lay Language

It is a common phenomenon that core temperature decreases below 36,0°C during and after surgery. For this reason core temperature will be analyzed before induction of anesthesia. Then patients below 36,0°C before anesthesia will be counted (=incidence) and patients below 36,0°C with those over 36,0°C will be compared to find risk factors. Sex, age, height, and weight will be collected. This study integrates data from seven prior studies of the University of Goettingen.

Brief Summary in Scientific Language

**Background: Hypothermia (< 36,0C°) is a common side effect of anesthesia and is associated with adverse patient outcome.
Hypothesis: high incidence of hypothermia already before anesthesia and surgery.
Methods: Measuring core temperature before induction of anesthesia, including patients with elective surgeries. Potential risk factors will be documented.
Analysis: Analysis of incidence of hypothermia before induction of anesthesia and multivariate Analysis of potential risk factors of hypothermia before induction of anesthesia.**

Organizational Data

- DRKS-ID: **DRKS00005109**
- Date of Registration in DRKS: **2013/11/15**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: [---]*
- (leading) Ethics Committee Nr.: [---]*



Secondary IDs

Health condition or Problem studied

- Free text: **Hypothermia**

Interventions/Observational Groups

- Arm 1: **Background:** Hypothermia (< 36,0C°) is a common side effect of anesthesia and is associated with adverse patient outcome.
Hypothesis: high incidence of hypothermia already before anesthesia and surgery.
Methods: Measuring core temperature before induction of anesthesia, including patients with elective surgeries. Potential risk factors will be documented.
Analysis: Analysis of incidence of hypothermia before induction of anesthesia and multivariate Analysis of potential risk factors of hypothermia before induction of anesthesia.
Grouping of patients for Analysis:
Group 1: > 36,0°C core temperature before induction of anesthesia
Group 2 < 36,0°C before induction of anesthesia

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Prevention**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

**Incidence of Hypothermia
measured with Thermometer before induction of anesthesia**

Secondary Outcome

Median of core temperature calculated, calculation and identification of risk factors: Age, weight, height, sex. Data is collected from the intraoperative anesthesia document. Further calculated risk factors: Body Mass Index, lean body weight, adipose Ratio.

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Anästhesie, Göttingen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/01/01**
- Target Sample Size: **525**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

**complete Data sets
elective surgery**

Exclusion criteria

< 18 years, thyroid disease, pregnancy, ambulant surgery

Addresses

- **Primary Sponsor**
Universitätsmedizin Göttingen



Primary Sponsor

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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Deutsches Register
Klinischer Studien

German Clinical
Trials Register

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/12/02**

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.