



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

Trial Description

Title

Perioperative trend of body core temperature in patients undergoing elective trauma and orthopedic surgery

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Before, during or after surgery patients are exposed to a variety of factors limiting their ability to maintain their body core temperature. As a consequence many patients experience an inadvertent perioperative drop in body core temperature, a hypothermia.

Many trials found hypothermia to be associated with increased risk of complications.

In addition to cardiac events, surgical site infections are often associated with hypothermia and directly linked to worse outcome. Due to the fact that the current literature is mainly based on patients from a general surgical or gynecological population the incidence of hypothermia and related complications like surgical site infections is unclear and therefor the topic of this study.

Brief Summary in Scientific Language

observational study to gain knowledge in terms of the incidence and the relevance to the outcome of perioperative hypothermia in patients undergoing elective trauma or orthopedic surgery

Organizational Data

- DRKS-ID: **DRKS00012878**
- Date of Registration in DRKS: **2018/02/28**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **17-6095-BR , Ethik-Kommission der Medizinischen Fakultät der Ruhr-Universität Bochum**



Secondary IDs

Health condition or Problem studied

- ICD10: **T84.6 - Infection and inflammatory reaction due to internal fixation device [any site]**
- ICD10: **T81.4 - Infection following a procedure, not elsewhere classified**
- ICD10: **T88.5 - Other complications of anaesthesia**

Interventions/Observational Groups

- Arm 1: **The body core temperature of Patients undergoing elective orthopedic or trauma surgery is measured in the preoperative setting. Patients are examined for postoperative complications.**

Characteristics

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

Primary Outcome

**perioperative hypothermia (POH);
Incidences of surgical site infections;
Incidence of postoperative cardiac or respiratory infections;
intraoperative blood loss and transfusion need;
postoperative mortality**

Secondary Outcome

patient factors contributing to the development of POH; surgical site and duration of surgery



patient factors contributing to the development of POH; surgical site and duration of surgery

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **BG Universitätsklinikum Bergmannsheil Bochum, Bochum**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/11/27**
- Target Sample Size: **1000**
- 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

elective orthopedic or trauma surgery

Exclusion criteria

colonisation or infection with multiresistent germs; open fractures; patient not fully legal competent

Addresses

- **Primary Sponsor**
BG Universitätsklinikum Bergmannsheil Bochum



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)**

Berufsgenossenschaftliches Universitätsklinikum Bergmannsheil GmbH

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Deutsches Register
Klinischer Studien

German Clinical
Trials Register

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

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URL: **www.bergmannsheil.de**

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]*

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.