Trial Description

Title

Difference in wound temperature in parturients scheduled for elective cesarean delivery with and without preoperative active warming.

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Preoperative active warming has been associated with improved maternal thermal comfort, less shivering and improvement in neonatal acid base status (Horn et al., 2014; Sultan et al., 2015). In this study, we would like to elucidate the effects of prewarming on the wound temperatures during surgery for caesarian section, because low intraoperative wound temperatures might be associated with an increased risk of postoperative wound infections.

Brief Summary in Scientific Language

Preoperative active warming has been associated with improved maternal thermal comfort, less shivering and improvement in neonatal acid base status (Horn et al., 2014; Sultan et al., 2015). In this study, we would like to elucidate the effects of prewarming on the wound temperatures during surgery for caesarian section, because low intraoperative wound temperatures might be associated with an increased risk of postoperative wound infections.

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00018974**
- Date of Registration in DRKS: **2020/02/27**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

DRKS-ID: **DRKS00018974**
Date of Registration in DRKS: **2020/02/27**
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.: **691 , Ethik-Kommission der Ärztekammer Bremen**

Secondary IDs

Health condition or Problem studied

- ICD10: **O82 - Single delivery by caesarean section**
- ICD10: **T68 - Hypothermia**

Interventions/Observational Groups

- Arm 1: **Prewarming**
- Arm 2: **No prewarming (control)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **data analyst**
- Control: **Control group receives no treatment**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Wound temperature after childbirth and before skin closure, measured by thermophotography

Secondary Outcome

Core temperature, patient comfort

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Klinikum Bremerhaven-Reinkenheide, Bremerhaven**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2020/03/01**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

scheduled for primary c-section

Exclusion criteria

- Refusal
- known allergies gainst substances used during routine c-sections
- impaired thermoregulation (e.g. fever, hypothyreosis)
- scheduled for post-op ICU stay, h/o eclampsia or preeclampsia
- patients who are unable to understand and consent to the study

Addresses

■ **Primary Sponsor**

Klinikum Bremerhaven-Reinkenheide
Mr. Pd Dr. med. Oliver Radke
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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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Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

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

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Votum Ethikkommission**
- trial protocol (mandatory for transfer to Studybox) **Studienprotokoll**

** 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.*