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The optimal warming strategy to reduce low body temperature during surgery

Submission date
08/03/2024

Recruitment status
No longer recruiting

Registration date
11/03/2024

Overall study status
Completed

Last Edited
16/06/2025

Condition category
Surgery

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Patients having surgery with anesthesia often lose body heat and become cold during the surgery. This can be associated with discomfort and, if significant, with medical side effects such as abnormal heart rhythm. A variety of methods and devices exist to warm patients up and/or prevent loss of body heat. While these are used routinely and are approved by regulatory agencies around the world, and are safe and (mostly) external to the body, the optimal combination and timing of their use is not entirely clear. The purpose of this study is to find out which of four combinations of warming strategies is optimal for these patients.

Who can participate?
Men and women at least 18 years of age, who are having elective abdominal, gynecologic, breast surgery, plastic/reconstructive or urological surgery under general anesthesia, where the operation is projected to last longer than 1.5 hours but less than 4 hours.

What does the study involve?
The patients will be randomly assigned to four groups that represent combinations of warming strategies. Group 1 will have an electrical warming blanket (conductive warming, or CW) used before their surgery and during their surgery. Group 2 will have a forced air blanket (FAW) used before and during their surgery. Group 3 will have no active warming before surgery and CW during surgery, but warm cotton blankets before the surgery will be allowed if patient wants to use them. And 4) will have no active warming before surgery and FAW during the surgery. Again in group 4 warm cotton blankets before the surgery will be allowed. All of these warming methods (CW and FAW) are well-established in practice and are achieved with common equipment. No method in and of itself is novel or lacking regulatory approval. All these methods are non-invasive.

What are the possible benefits and risks of participating?
The possible benefits are that if one of these groups turns out to be a superior strategy for keeping the patients warm, then those who have been assigned to that group will be more comfortable and/or will lose less body heat during their surgery. The risks are that the patient may have been assigned in a group where they will lose more body heat during the surgery.

Where is the study run from?
Cooper University HealthCare, New Jersey, USA.

When is the study starting and how long is it expected to run for?
February 2018 to August 2022

Who is funding the study?
Augustine Medical Inc., Eden Prairie, MN, USA

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The optimal warming strategy to reduce perioperative hypothermia: a prospective randomized non-blinded clinical trial

Study objectives
1. Active warming with a conductive warming system (CW) will be non-inferior in preventing hypothermia when compared to active warming with a forced air warming system (FAW).
2. Active preoperative warming with CW or FAW will lead to a reduction in intraoperative hypothermia when compared with only intraoperative warming with CW or FAW.
3. Active preoperative warming combined with intraoperative warming using CW is a superior strategy compared to only intra-operative warming with the CW, intraoperative warming with FAW only, or pre-operative and intra-operative warming with FAW.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/09/2019, Cooper University HealthCare IRB (One Cooper Plaza, Camden, NJ, 08103, United States of America; +1 (856) 757-7832; IRBOnlineHelp@cooperhealth.edu), ref: 18-148

Study design
Prospective randomized non-blinded investigator-initiated clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
See outputs table

Health condition(s) or problem(s) studied
Patients having surgery with general anesthesia

Interventions
Participants are randomized to four groups, each representing a different preoperative warming approach:
1. Conductive prewarming (CW) and conductive intraoperative warming i.e. CW+CW;
2. Forced air (FAW) prewarming with forced air intraoperative warming i.e. FAW+FAW;
3. No active prewarming (NAPW) with conductive intraoperative warming i.e. NAPW+CW; and
4. No active prewarming (NAPW) with forced air intraoperative warming i.e. NAPW+FAW.

Of note, all of these warming methods are well-established in practice and are achieved with commonly available methods/equipment. No method in and of itself is novel or lacking regulatory approval. All these methods are non-invasive.

Duration of intervention: from signing of informed consent form and/or arrival to pre-operative surgical area (if form was signed ahead of time), to end of surgery.

Duration of follow-up: 30 days post-surgery.

Randomisation: we used a computer generated randomization list (Excel) to allocate subjects to one of four warming strategies in a 1:1:1:1 ratio. We used block randomization for scheduled surgical strata (1.5 h – 2.5 h and 2.5 – 4 h) and type of surgery (abdominal, gynecologic, breast surgery, plastic/reconstructive, urologic surgery) to ensure equal distribution of likely confounding variables.

Intervention Type
Procedure/Surgery

Primary outcome measure
Intraoperative hypothermia magnitude will be the primary outcome. Hypothermia will be defined as a core temperature <36 °C and quantified as the intraoperative area under the curve (AUC) < 36 °C (units °C*hr) detected with an esophageal temperature probe.

Secondary outcome measures
1. Lowest temperature measured intraoperatively: degrees C, measured via esophageal temperature probe. Recorded in the electronic anesthesia record.
2. The percentage of the time of the case spent hypothermic: unit is minutes. Measured as the time in minutes under 36 degrees C divided by the duration of the operation (surgery) in minutes x 100. Times obtained from the electronic anesthesia record.
3. The absolute incidence of hypothermia: this is a binary score. I.e. if body temperature dropped below 36 degrees C at any point during the surgery, it was a yes. If not, then no.
4. The thermal comfort score: ordinal 5-point patient-reported Likert scale. Obtained by study coordinator at the end of the patient's stay in the pre-operative area, i.e. just before transfer to the operating room. See attached PDF for the Likert scale questions.

Overall study start date
03/02/2018

Completion date
08/08/2022

Eligibility

Key inclusion criteria
1. Subjects undergoing elective abdominal, gynecologic, breast surgery, plastic/reconstructive or urological surgery under general anesthesia
2. Surgery projected to last longer than 1.5 hours, but no longer than 4 hours

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
184

Total final enrolment
184

Key exclusion criteria
1. Cardiac surgery
2. Vascular surgery
3. Pregnancy
4. Age < 18 years
5. Imprisonment
6. Inability to provide written informed consent
7. Inability to speak and/or read English

Date of first enrolment
04/12/2019

Date of final enrolment
08/08/2022

Locations

Countries of recruitment
United States of America

Study participating centre
Cooper University healthcare
One Cooper Plaza
Camden, NJ
United States of America
08103

Sponsor information

Organisation
Cooper University HealthCare, Department of Anesthesiology

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Sponsor type
Hospital/treatment centre

Website
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Funder(s)

Funder type
Not defined

Funder Name
Augustine Medical Inc., Eden Prairie, MN, USA

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal (PLoS One).

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The full dataset will be uploaded into https://datadryad.org/stash before submission to a journal for peer review.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			11/03/2024	No	Yes
Protocol file		22/05/2019	11/03/2024	No	No
Results article		12/06/2025	16/06/2025	Yes	No