

# The optimal warming strategy to reduce low body temperature during surgery

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<b>Registration date</b> 11/03/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/06/2025	<b>Condition category</b> Surgery	<input type="checkbox"/> 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?  
Dr. Ronak Desai, D.O., Desai-ronak@cooperhealth.edu

## 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**

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## **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  $<36^{\circ}\text{C}$  and quantified as the intraoperative area under the curve (AUC)  $< 36^{\circ}\text{C}$  (units  $^{\circ}\text{C}\cdot\text{hr}$ ) 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  $\times 100$ . 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

### Sponsor details

One Cooper Plaza  
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### Sponsor type

Hospital/treatment centre

### Website

<https://cooperhealth.edu>

## 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?
<a href="#">Participant information sheet</a>			11/03/2024	No	Yes
<a href="#">Protocol file</a>		22/05/2019	11/03/2024	No	No
<a href="#">Results article</a>		12/06/2025	16/06/2025	Yes	No