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PHRES Study: A Prospective Multicenter Observational Study of the Prevalence of Postoperative Hypothermia in Adults Undergoing Non-Cardiac Surgery in Spanish Post-Anesthesia Care Units

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1. Study Identification

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2. Study Summary

PHRES is a prospective, multicenter, observational study designed to determine the prevalence of unintended postoperative hypothermia in post-anesthesia care and postoperative critical care units in Spanish hospitals. The study will also describe perioperative temperature-management practices, investigate factors associated with postoperative hypothermia, and assess immediate postoperative complications associated with low core temperature.

The study is expected to include 1,334 adults undergoing scheduled non-cardiac surgery under general, neuraxial, or combined anesthesia. Approximately 25–30 participating hospitals are expected. Recruitment will be simultaneous across centers for four weeks, with patients enrolled consecutively during two to three recruitment days per week according to each center's organization.

The study does not assign or modify perioperative warming or temperature-monitoring strategies. The treating anesthesia team will manage temperature according to local clinical practice. The only study-specific procedure is a non-invasive measurement of core temperature on admission to the post-anesthesia care unit using the same zero-heat-flux temperature monitoring system at all participating centers.

3. Background and Rationale

Unintended perioperative hypothermia remains a frequent clinical problem associated with potentially important complications. Patients undergoing surgery are exposed to multiple factors that can lower core temperature, including the effects of anesthesia on thermoregulation, redistribution of heat from the core to peripheral tissues, exposure to the operating-room environment, surgical duration and exposure, and administration of intravenous or irrigation fluids.

During the first hour after induction of anesthesia, core temperature may decrease substantially because anesthetic drugs impair normal thermoregulatory responses and promote redistribution of heat. The lack of consistent core-temperature monitoring and variation in the use and effectiveness of warming strategies may contribute to inadequate prevention and treatment of perioperative hypothermia.

Reported complications associated with perioperative hypothermia include increased bleeding and transfusion requirements, cardiovascular complications, delayed post-anesthetic recovery, shivering and discomfort, and other adverse postoperative outcomes. These complications may also increase healthcare resource use and negatively affect the patient experience.

In 2019, Alfonsi et al. reported a prospective multicenter observational study in France including 893 non-cardiac surgical procedures from 52 hospitals. Despite frequent use of active warming and temperature monitoring, the prevalence of hypothermia on admission to recovery units was 52%. The authors concluded that greater use of available warming technologies and temperature monitoring was warranted.

4. Hypothesis and Objectives

Hypothesis: Despite the availability of active warming technologies and core-temperature monitoring, their use is not universal in Spanish hospitals. The study hypothesizes that the prevalence of postoperative hypothermia in post-anesthesia recovery units in Spain will be similar to that reported in the French multicenter study and will be greater than 50%.

Primary Objective: To determine the prevalence of postoperative hypothermia in post-anesthesia recovery units in Spanish hospitals.

Secondary Objectives: (1) To determine the prevalence of preoperative active warming (prewarming), intraoperative active warming, and intraoperative core-temperature monitoring; (2) to investigate patient-, procedure-, and temperature-management factors associated with postoperative hypothermia; and (3) to assess immediate postoperative complications associated with postoperative hypothermia.

5. Study Design

Design: Prospective, multicenter, observational study.

The study has been designed in accordance with international STROBE recommendations for observational studies.

The study will be conducted in public, private, or publicly managed private hospitals whose operating departments have active intraoperative warming systems and availability of postoperative core-temperature monitoring. Participating centers will be recruited through the network of the Sociedad Española de Anestesia y Reanimación (SEDAR) and other professional contacts.

6. Study Population and Eligibility

The study population will consist of adult patients undergoing scheduled non-cardiac surgery at participating Spanish hospitals. Eligible patients will be identified on the day of surgery.

6.1 Inclusion Criteria

- Age ≥18 years.
- Written informed consent provided by the participant.
- American Society of Anesthesiologists (ASA) physical status I–III.
- Scheduled non-cardiac surgical procedure.
- Anesthesia duration >60 minutes.
- General anesthesia, neuraxial anesthesia, or combined general and neuraxial/peripheral nerve block anesthesia.

6.2 Exclusion Criteria

- Signs or suspicion of infection.
- Surgical procedures performed under regional nerve blocks and/or sedation only.
- Cognitive impairment or inability to understand the study information.
- Refusal to participate.

7. Sample Size

The sample size was calculated assuming an expected postoperative hypothermia prevalence of at least 50%. Using the conservative value p=0.50, an absolute precision of ±3%, a two-sided alpha of 0.05, and Z=1.96 for a 95% confidence level, the initial required sample size was 1,067 patients. Assuming that approximately 20% of collected data could be unusable, the target sample size was increased to 1,334 patients.

8. Recruitment

Participating centers must commit to recruiting a minimum of 25 patients, with an ideal target of 50 patients depending on their clinical capacity. Recruitment will be conducted simultaneously across centers over a four-week period, with two to three recruitment days per week according to the organization of each center.

Patients will be enrolled consecutively among those meeting the eligibility criteria until the planned overall sample size is reached. Each center will have a principal investigator (PI). An additional collaborator may be included for every 25 patients recruited in that center.

9. Study Procedures

Two study visits are planned.

Visit 1 – Preoperative area: patient eligibility will be assessed; the study will be explained verbally and in writing; and written informed consent will be obtained.

Visit 2 – Admission to the postoperative recovery area: data will be collected from the medical record and anesthesia chart; core temperature will be measured; and immediate postoperative complications potentially associated with hypothermia will be documented.

The study will not modify the temperature-management strategy in the operating room or recovery unit. The treating anesthesiologist will decide whether to use active warming and intraoperative temperature monitoring according to local protocols and routine clinical practice.

10. Postoperative Temperature Measurement

To minimize measurement bias caused by differences in temperature-monitoring technology or measurement site, the same postoperative core-temperature monitoring method will be used in all study participants. The device is the BHTMS (3M™ Bair Hugger™ Temperature Monitoring Patient Sensors, 36000), a non-invasive zero-heat-flux temperature monitoring system with a forehead sensor.

The sensor is placed on the forehead and provides a non-invasive estimate of core temperature. The study does not aim to validate the monitoring device. Previous studies have compared zero-heat-flux temperature monitoring with established core-temperature measurement methods.

The device is available at participating centers and is used in accordance with its approved clinical indication. Its use in the study consists of placing a non-invasive adhesive sensor on the forehead and is not expected to modify routine clinical management or create significant additional risk.

11. Variables and Data Collection

Center-level variables will include type of hospital management, number of beds, annual number of surgical procedures, number of operating rooms, ambulatory-surgery rate, surgical specialties, existence of an institutional perioperative-hypothermia prevention protocol, and available warming and core-temperature monitoring technologies.

Patient-level variables will include age, sex, weight, height, body mass index, ASA physical status, hypertension, diabetes treated with oral medication or insulin, active smoking, peripheral vascular disease, cerebrovascular disease, ischemic heart disease, and serum creatinine >2 mg/dL.

Procedure-level variables will include anesthesia duration, anesthesia technique, surgical specialty, open versus minimally invasive approach, use of irrigation fluids, use of vasoactive drugs, and fluid administration.

Perioperative temperature-management variables will include prewarming for at least 10 minutes before transfer to the operating room, intraoperative active warming and its method, and intraoperative core-temperature monitoring and its method.

Postoperative variables will include core temperature at admission to the recovery unit, shivering, Richmond Agitation-Sedation Scale (RASS), hemodynamic instability requiring vasoactive drugs, new-onset perioperative arrhythmia, perioperative bleeding >500 mL, and need for blood-product transfusion.

12. Outcome Measures

Primary Outcome: Prevalence of postoperative hypothermia, defined as the proportion of participants with a core body temperature <36.0°C at admission to the post-anesthesia care unit.

Secondary Outcome 1: Prevalence of preoperative active warming, defined as active warming for at least 10 minutes before transfer to the operating room.

Secondary Outcome 2: Prevalence of intraoperative active warming and description of the warming method used.

Secondary Outcome 3: Prevalence of intraoperative core-temperature monitoring and description of the monitoring method used.

Secondary Outcome 4: Patient-, procedure-, and perioperative temperature-management factors associated with postoperative hypothermia.

Secondary Outcome 5: Immediate postoperative complications associated with postoperative hypothermia, including shivering, hemodynamic instability requiring vasoactive drugs, new-onset perioperative arrhythmia, perioperative bleeding >500 mL, and need for blood-product transfusion.

13. Statistical Analysis

Statistical analyses will use a two-sided significance level of alpha=0.05. Current versions of SPSS, R, or equivalent validated statistical software may be used.

Descriptive analysis: categorical variables will be presented as absolute frequencies and percentages with 95% confidence intervals. Continuous variables will be described using mean and standard deviation or median and interquartile range according to the distribution of the data. Distribution may be assessed using tests such as Kolmogorov–Smirnov or Shapiro–Wilk.

Primary analysis: postoperative hypothermia prevalence will be estimated as a proportion with a 95% confidence interval.

Bivariate analysis: associations between hypothermia and independent variables will be explored using the chi-square test or Fisher exact test for categorical variables and the Student t test or Mann–Whitney U test for continuous variables, as appropriate.

Multivariable analysis: independent factors associated with postoperative hypothermia will be evaluated using binary logistic regression, with hypothermia (yes/no) as the dependent variable. Variables of clinical relevance or variables associated with hypothermia at $p<0.10$ in bivariate analysis may be considered for the model. Results will be reported as odds ratios with 95% confidence intervals. Collinearity and both statistical and clinical relevance will be considered. If the number of centers permits, a mixed-effects logistic regression model with center as a random effect will be considered.

Missing data: the amount and pattern of missing data will be assessed. If missingness is below 5%, complete-case analysis will be used. If missingness is higher, multiple imputation may be considered when methodologically appropriate. The primary outcome will not be imputed.

Sensitivity analysis: sensitivity analyses may be performed to assess robustness, for example by excluding centers with a high proportion of missing data or assessing stability of the multivariable model under different assumptions.

14. Safety and Adverse Events

This is an observational, low-risk study. The only study-specific procedure is non-invasive postoperative core-temperature measurement. No study-related adverse events are anticipated from this measurement.

15. Ethical Considerations

The study has been approved by the Ethics Committee for Research/Medicines Research Ethics Committee of Hospital Universitario Fundación Jiménez Díaz on 14 July 2026 (CEI code: EO150-26_FJD). The study will subsequently be submitted to the appropriate ethics committee or institutional authority at participating centers, according to applicable regulations. Recruitment at each center will begin only after the required local authorization and institutional approval have been obtained.

The study will be conducted in accordance with the Declaration of Helsinki and Good Clinical Practice recommendations.

All participants will receive information about the study objectives and procedures before participation and will provide written informed consent. Participants may withdraw consent at any time without affecting their clinical care.

16. Data Protection and Confidentiality

Personal data will be processed in accordance with Regulation (EU) 2016/679 (General Data Protection Regulation) and Spanish Organic Law 3/2018 on the Protection of Personal Data and guarantee of digital rights.

Study data will be pseudonymized using a unique participant code. The correspondence between the code and participant identity will remain exclusively at each participating center under the custody of the local principal investigator in a separate protected list accessible only to authorized personnel. Direct identifiers such as name, surname, medical record number, address, or social security number will not be entered into the study database.

Data will be collected in a structured electronic database with restricted access (miEstudio), including user authentication, activity logging, and periodic backups. Access will be limited to authorized investigators according to their study responsibilities. Data integrity, confidentiality, availability, and traceability of changes will be maintained.

Study data will be retained for at least five years after study completion in accordance with applicable requirements and will subsequently be securely destroyed or anonymized.

17. Study Procedures, Training and Quality Control

A study-specific Standard Operating Procedure (SOP) manual will provide instructions for temperature measurement, definitions of postoperative complications, and completion of the electronic case report form. Local investigators will receive online training before recruitment begins, focusing on variable definitions and data entry.

Because this is a low-risk observational study, routine external systematic audits are not planned. The sponsor may perform targeted audits and data reviews at selected centers. Centralized quality-control procedures may also be used, including consistency checks and feedback to centers when data-quality problems are identified.

18. Insurance and Funding

Because the study is observational and low risk, and the only study-specific procedure is non-invasive core-temperature measurement, no additional study-specific civil liability insurance is considered necessary.

The study is an independent investigator-initiated project without specific external funding. No financial compensation will be provided to participants or investigators.

19. Publication and Dissemination

Because this is a prospective study, it will be registered in a publicly accessible database before enrollment of the first participant. Study results will be reported and disseminated regardless of whether the findings are positive or negative.

The first author and corresponding author will be the principal investigator. The coordinating study group will appear as lead authors. Principal investigators from participating centers will be identified as PHRES Study Group investigators, and collaborators will be listed in an appendix or supplementary material as appropriate.

20. References

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