Clinical Optimization of Ambient Temperature and Heating Methods in Caring in Major Burns Patients

Optimal Heating Temperature in Major Burns Patients

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Study Protocol, Statistical Analysis Plan (SAP), Informed Consent Form (ICF)

Version 1.0

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HeatingBurns01- Study Protocol, Statistical Analysis Plan (SAP), Informed Consent Form (ICF)

1. Material and methods

6.1 Design, methodology and justification:

Pre-experimental pre-experimental epidemiological study without control group, in large burnt patients that will evaluate the influence on the metabolic expenditure of the inclusion of active external overheating in the control of ambient temperature adjusted to thermal comfort.. Two methods of active external heating, thermal plate and convective air blanket shall be used. Metabolic expenditure shall be measured by indirect calorimetry in the usual treatment with passive external overheating and post-intervention in the combination of passive and active external warming.

Sand pre-study thecombination of passive and active external overheating by measuring the operating temperature in various cases for optimal application, as well as the definition of thermal comfort in the unit of large burns. In this way, two study stages are integrated as shown in *Table 5*..

Table 5: Study stages Clinical optimization of ambient temperature and heating methods in the care of the patient large burned according to thermal comfort

Stage 1	Stage 2
Empirical study of operating temperature according to the combination of passive and active external heating methods for the definition of environmental comfort.	Quasi-experimental study of large burned patients to study the impact on metabolic expenditure of the inclusion of active external overheating in environmental temperature control

6.2. Population and sample:

6.2.1. Target population

Burnt patients receiving treatment in large burnt units that require heating for the maintenance of normothermia and prevention of hypothermia. In 2017, 9186 burn hospitalizations were recorded, with a national incidence of 7 cases per 100,000 inhabitants.

6.2.2. Accessible population

Patients with thermal burns admitted to the burn unit of the Río Hortega Hospital in Valladolid since March 2020 who do not meet exclusion criteria. Sand reached 30 patients admitted in 2018 for thermal burns. Although the unit, a reference in Castile and León for the care of burn patients, serves a population of 2,419.00 inhabitants

6.2.3. Sampling design

Sampling in the selection of patients shall be per snowball,all participants in the centre shall be included until sample saturation or until 18 months after the start of the study, in which metabolic expenditure will be assessed in all 3 cases: passive external overheating, thermal plate overheating and convective air blanket overheating.

6.2.4. Sample size

Using the GRANMO sample matingc, Version 7.12 was calculated for the difference of media coupled in energy expenditure at rest of the combination of passive and active external (in two methods, by thermal plate and convective air blanket) versus passive external heating.

Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a bilateral contrast, 34 subjects are required to detect a difference equal to or greater than 0.15 units. A standard deviation of 0.3 is assumed. A 5% tracking loss rate has been estimated.

The difference expected to be found in the resting metabolic expenditure rate of at least 0.1 times the GMB. The increase in baseline metabolic expenditure of these patients in studies with burned patients was 1.4 times with standard deviation of 0.2 – 0.32 times. The sample will be adjusted to the standard deviation values presented in the pilot sample.

6.2.5. Inclusion criteria

- Patients over the age of 18.
- Patients with thermal burns.
- Patient with high burn criteria according to ABA:
    - 2nd grade burn
        - Patient 18 – 59 years: SCQ > 20 %
        - Patient > 60 years or pathology: SCQ > 10 %
    - 3rd degree burn
        - SCQ > 10 %
- Patients in mechanical ventilation.

6.2.6 Exclusion criteria

- Sepsis criteria according to ABA.
- Application of debridenenzymatic (data in the next 24 hours).
- 6 hours after surgery.
- After 2 hours after healing the burns

- Patients in hemorrhagic shock.

6.3. Variables

Sociodemographic data will be collected from the patients included in the study: age, sex, days of entry into burn unit, early and hospital mortality. Personal background data, previouspathologies. Variables about the burn will be included: Body Surface (BSA) in m^2, Burned Body Surface (SCQ) in m^2 and %, Deep Burned Body Surface (SCQP) in %, origin of the burn.

6.3.1. Dependent variables

At the stage of defining thermal comfort, the variables shall be collected:

- Operating temperature (Dry temperature + radiant temperature)
- Relative humidity
- Air speed

For the assessment of nutritional data and energy expenditure, the variables will be collected: Weight, Height, Ideal Weight, BMI (kg/m^2), FiO_2, Charlson Index, Nutri- Score, Nutritional Biochemistry, Serum Albumin (g/dl). The calculation of theoretical caloric requirements (kcal/day) using the Penn State predictive formula and the protein requirements/day (gr/day) calculation will be included.

- Metabolic expenditure, calculated by Indirect calorimetry collecting the variables:
  - VCO_2: Carbon dioxide production (Avg VCO_2, VCO_2 hp)
  - VO_2: Consumption of O_2 (Avg VO_2,VO_2 HP)
  - RQ: Cociente respiratorio (Avg RQ, Avg EE)
  - EE: Energy expenditure in kcal/d (Avg EE/m^2, AVG EE/Kg)
- Body temperature via surface thermometer
- Central temperature recorded by bladder probethermometer, from entry and registration c/8h until 7 days after admission. Time recording of temperature during heating analysis.
- Calculation of liquid loss estimation.

The difference of the metabolic state at rest versus the actual one will be categorized by qualitative scale.

Due to the critical condition of the patient, the CONFORT scale will be collected for the evaluation of sedation and pain in the critical patient.

For the assessment of the comfort status (NOC 2008) and thermoregulation (NOC 0800) according to Thert scale will be carried out in the application of the two heating techniques.

6.3.2. Independent variables

- Passive external heating: Ambient temperature value in oC Programmable *ambient temperature,* with ambient temperature programming capability in range of *18 to 35 oC* with accuracy of +-0.1oC, and driven pressure of *+15 Pa.*.
- Active external heating:
  - By radiant plate: Patient distance, heating level and control temperature on skin. Application time.
    - Aspira Medical AB Aragonia thermal plate ® MTC 400 CE 0413 certified. It is a height heating device adjustable up to 50 cm from the patient generates radiant heat at low temperature (up to 39oC) evenly distributed. It is equipped with an adjustable potentiometer of 0- 9 and has a temperature probe on the skin as a control and safety mechanism.
- Convective air blanket: Application start, Heating power level (35-38-43oC). Application time
    - Equator Level 1® of Smiths Medical REF EQ-5000, CE 0473 certified,consisting of a unit that produces hot air and adjustable forced air from 38oC to 43oC.. It sends the hot forced air distributed by tubular blanket that convectively heats the patient by spreading the hot air directed towards the patient through the textile pore of the air blanket.

- Factors that decrease hyper-metabolic response:
    - Blood glucose monitoring.
    - Administration of Glutamine Supplement[59].
    - B-blocker drugs: propanolol, oxandrolone... (Dismimuirán the GMB)
    - Caloric dose of enteral nutrition. (Sufficient, scarce augmented by the

6.4. Instruments collecting information

Climate comfort measurement

Testo® 435 multifunction air conditioning meter, which performs the necessary measurements to adjust the ventilation and air conditioning systems[75]. The different pluggable sensors and probes will provide the variables to study::

- Thermal speed probe: air speed and volumetric flow rate.
- IAQ (Indoor Air Quality) probe to evaluate air quality measures CO2, ambient temperature, ambient humidity and absolute pressure.
- Balloon probe to measure thermal radiation
- Temperature probe to measure ambient temperature, indoor temperature and surface temperature. Both with measurement accuracy +/- 0.1 oC
- *Location of measures*
    - At patient bed level:
    - 4 measurement points and extrapolate the results assuming radiant symmetry conditions, would allow to extrapolate results to the entire object area: patient's head and trunk and staff positions at the patient's head and trunk height
    - 2 radiant plate positions: the nearest (50 cm) and 1 meter, distance when the worker's position is simulated in the patient's environment.
    - At the worker's level: 2 positions, at the bedside and on the patient's trunk 50 cm from the center of the bed.
    - Media of the convective air blanket in the functions of 38o and 43oC, calculating temperature, humidity and speed..

<u>Calculation of metabolic expenditure by Indirect Calorimetry and Temperature:</u>

- Carescape R860® of Datex Ohmeda CE certified with the GE Healthcare Adult D-Lite+ Spirometry Kit with CE 0537 certification. GE CARESCAPE™, is a fan that has an integrated module that can measure the energy expenditure of patients through indirect calorimetry[76].

- Central temperature:
    - Vesical probe with 16fr MDCON SV temperature sensor registered in Philips Monitor® IntelliVue MP5.
- Body temperature:
    -

6.4.1 Data collection sheet

The study variables will be collected in the Microsoft Excel database® as seen in *Annex I.*. Patients shall be coded with an assigned number that does not permit identification by a specific independent sheet intended for this purpose.

A collection sheet model for data collection will be distributed with explanatory instructions for research partners.

For the collection of sociodemographic data and study variables, it will be necessary to access the patient's medical history with the data that are entered into the program and those automatically recorded to the Philips Intelli Vue® medical history.

6.4.2 Data collection

For the analysis of thermal comfort, the suppliedam biennage temperatureshall be analysed in the values: minimum of 25oC, 28oC, 31oC as shown in Table *6.*. . The ambient temperature of 33oC is obvious, as it is considered that in combination with the elements of active external overheating average conditions of 33oC are reached. The graphical representation of the

Table 6: Scenario of combination analysis of heating methods

Registration No.	Ambient temperature		
	25oC	28oC	31oC
Thermal plate at 50 cm	1	3	5
Thermal plate at 100 cm	2	4	6
Convective air blanket 38oC			
Convective air blanket 43oC			

measures shall be carried out as represented in *Annexess IV* and *V*.

The convective air blanket, by the heating mechanism, an analysis will be carried out, studying the theoretical effect combined with the ambient temperature.

Sociodemographic and nutritional data of the patient will be collected after acceptance and signature of the informed consent that will be collected in the first days after the patient's entry into the burn unit. Variables will be collected during the night shift (22:00 to 8:00) because there are no scheduled tasks of cures, diagnostic tests or surgical intervention that may alter both the care activity in the unit and the alteration of variables to be collected. Data will be collected for 6 hours from the intervention: evolution of body and central temperature and metabolic expenditure calculated in 24 hours. From the third day after the burn, the 3 heating methods will be applied to study, on three consecutive nights

Night 1: Ambient temperature 32oC

Night 2: Ambient temperature and combination with thermal plate

Night 3: Ambient temperature and combination with thermal blanket.

6.4.3 Pilot test

A pilot test will be carried out with at least 2 patients to check the proper collection of variables and debugging of errors in the collection methods and the adequacy of the heating application times and inclusion of the variables.

6.5. Data analysis

The values of the temperatures measured in the empirical study, the discrete and absolute variables according to descriptive in ranges, maximum and minimum, trend, mean and median valuesshall berecorded.. The VMP and PPI values willbe calculatedthrough the software associated with the Testo® measuring instruments.

A descriptive analysis of the variables obtained shall be carried out. Continuous quantitative variables shall be analysed by the Kolmodorov-Smirnov test and described as mean standard deviation (DS) in case of normal distribution, or as median and range if the distribution does not follow the normal distribution. Qualitative variables shall be described by absolute and relative frequencies. A single-rate analysis shall be performed by observing as variables main dependent temperature and metabolic expenditure. With a 95% confidence interval ($p<0.05$) quantitative variable means will be contrasted using Student t or Mann-Whitney's U-depending on the sample distribution. The Chi-square test for contingency tables and the Fisher test will be used to assess association of qualitative variables.

A logistic regression model may be established based on the results, analyzing the strength of association in explanatory and predictive terms.

IBM SPSS Stadisticssoftware® v.23 will be used for statistical data analysis

6.6 Ethical Aspects

Confidentiality and custody of the data collected in the investigation will be ensured by coding the participants. A code will be assigned to each participant in a separate file to the data collection that will only be accessed by the principal investigator.

The research project is agreed with the principles of bioethics in biomedical research developed in the Helsinki Declaration ratified in Fortaleza (Brazil) in 2013 and the Oviedo Convention on the Protection of Human Rights and Dignity promoted by the Council of Europe and validated in 2000 in Spain.

The information provided to the participants ortheir representatives in compliance with the Biomedical Research Act 14/2007, of July 3,, will be provided through the patient information sheet.

The processing of the data of the study, access, confidentiality and privacy regulated by: Organic Law 15/1999, of December 13, Protection of Personal Data, Law 41/2002 of 14 November, basic regulation of patient autonomy and rights and obligations in the field of information and clinical documentation and updatingof Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data. The same, is declared compliance with regulations or regulations that may be ordered later at the beginning of the study.

In accordance with RD 223/2004, of February 6, the study will be evaluated by the Ethics Committee of Research with medicines of the health area Valladolid West assessing the methodology, ethical and legal aspect and balance of the risks and benefits in the realization of the study.

6.6.1 Statement of Interest

The Principal Investigator declares that he/she has no conflict of interest, no contractual relationship with the materials or products that are included in the study.

6.6.2 Informed information and consent sheet

An information sheet will be provided to participants (or representative if necessary), candidates for inclusion in the study informing about the content of the study, their participation and rights as reflected in *Annex III.*.

Acceptance of participation in the study will be reflected in the informed consent signed by the participant or his/her representative under the conditions shown in *Annex IV.*

RESEARCH STUDY PARTICIPANT REPORTING SHEET **INFORMACIÓN AL**

Burn Unit **Hospital**	Research Study Thermal comfort and clinical optimization of ambient temperature in high burned patient care	Fact Sheet Version 1.0

Principal investigator:

Contact:

Burn patients need specific care for maintaining body temperature and avoid hypothermia. Due to skin loss you have greater heat loss than healthy people. The usual care to treat this heat loss is to increase the temperature of the room to decrease the energy expenditure in the production of heat.

It is common for burn patients to have a higher temperature to healthy people, due to accelerated metabolism and high energy consumption while at rest. For this reason, high body temperature does not have to originate from an infection, so we value other clinical parameters and laboratory tests in order to differentiate its origin.

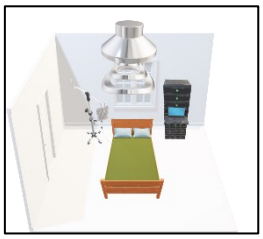
Studyobjective

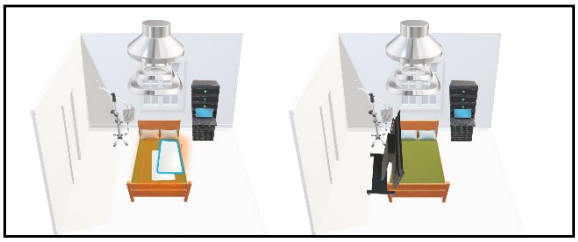
Your nurse's interest is to improve the care provided in the burn unit, knowing the maintenance of body temperature and improving the thermal comfort of patients and professionals. Although there are studies on environmental temperature and energy metabolism in burnt patients, they have not been conducted on the influence of external heating methods using hot blankets or thermal plates.

Intervention to be carried out in the study

Participation in the study will consist of applying a heating method, using a thermal plate that provides infrared heat used in our usual practice, or a warm air blanket also frequently used in the prevention of hypothermia in critical or surgical patients.

Before and after the application of the heating method, metabolic expenditure, which is the relationship between energy consumption and energy that the body needs, will be calculated to assess whether energy consumption needs decrease with the heating methods applied. To perform this calculation you will not need any additional intervention when performing through the fan that already provides breathing support.





Common practice Study combining heating methods

(High Ambient Temperature) (Hot Air Blanket) (Thermal Plate)

R benefits and benefits derived from participation in the study

There is no risk in your participation in the study, as common warming methods are studied in the care of patients with burns, this study will assess its application.

It may not provide direct benefit to the study participant, but it will serve to apply the heating methods optimally. Direct monitoring of energy expenditure parameters can guide the treatment of nutrition.

Communication of results

If you wish you will be provided with the results of the study at the completion of the study..

This research project has been approved by the Research Ethics Committee of the reference health area, ensuring compliance with the principles of bioethics in research and patient rights.

This project has requested the scientific endorsement of the Spanish Society of Intensive Nursing and Coronary Units in recognition in the training of the specialization in intensive nursing.

This project will be registered and available at ClinicalTrial.gov,as an ethical commitment to patients and the research process.

Howparticipant in thisstudy is important thatconozca several legal aspects:

- Your participation is entirelyvoluntary, your participation or revocation will not prejudice the health care you receive.
- You will not receive any financial or other compensation for your participation in the study.
- Personal data will be processed in accordance with the provisions of the regulations that apply, such as Regulation (EU) 2016/679, of 27 April, General for the Protection of Personal Data, and its implementing regulations both at national and European level.
- The recorded data will be processed statistically in a coded form. At all times the participant will have the right of access, modification, opposition, rectification or cancellation of the data deposited in the database when expressly requested. To do this, you must contact the lead investigator. The data will be kept under the responsibility of the Principal Investigator of the Estudio_____ Likewise, you have the right to contact the Data Protection Agency if you are not satisfied.
- The data will be stored indefinitely, which will allow it to be used by the lead researcher's group in future research studies related to the line ofwork.

Copy for the patient

Annex III:Patient Informed Consent

INFORMED CONSENT PARTICIPANT IN RESEARCH STUDY

	Research Study Thermal comfort and clinical optimization of ambient temperature in high burned patient care	Informed Consent Version 1.0

_____

(participant's first and lastname)

_____
_____
_____
____declaro:

(name and surname of the representative if applicable))

- I have read the information sheet and understood my participation in this study.
- I have been informed by

  _____

  _____

  _____

  (name and surname of the researcher)

  whom I've been able to ask questionsof.
- I participate freely and voluntarily after receiving the information
- I acknowledge my participation rights and may withdraw from the studio:
  - Anytime.
  - Without having to explain.
  - No repercussions for my care.

By signing this document I voluntarily consent to participate in this study and allow access to my dataconforms to me and has been given to me on the information sheet.n.

Date:

Signature of the participant or representative Signature of the Investigator

_____ _____

(first and last name) (first and last name)

Space reserved for the

REVOCATION OF CONSENT

I _____revoco consent to participate in the study.
(first and last name)

Signature: Date:.

Copy for the patient