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Body surface and core temperatures and their association with cardiac function

Submission date	Recruitment status	[ ] Prospectively registered
10/07/2019	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/07/2019	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/02/2024	Other	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Assessment of peripheral perfusion (blood flow) and comparison of surface and body core temperature (BST; BCT) are diagnostic cornerstones of critical care. Infrared non-contact thermometers provide easy and accurate measurement of BST. In clinical routine BCT is most frequently measured with ear thermometers in an intermittent way. The PiCCO device provides accurate measurement of Cardiac Index using an arterial line with a thermistor tip which is introduced into the distal aorta. Irrespectively of intermittent CI measurement, the PiCCO catheter provides continuous measurement of BCT.

Who can participate?
Patients in the intensive care unit undergoing transpulmonary thermodilution (PiCCO) monitoring

What does the study involve?
Repeated measurement of body surface and core temperatures as well as repeated measurement of cardiac index.

What are the possible benefits and risks of participating?
Patients may benefit from more intense monitoring during the study period. All methods are routine techniques with limited risks. Non-contact infrared thermometers are considered safe even when used by lays.

Where is the study run from?
Intensive Care Unit of Klinikum rechts der Isar; Technische Universität München (Germany)

When is the study starting and how long is it expected to run for?
July 2009 to December 2021

Who is funding the study?
Technische Universität München (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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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
Body surface and core temperatures to assess haemodynamics in critically ill patients

Acronym
BOSTON

Study objectives

Body surface temperatures, body core temperatures, structured clinical examination and biochemical markers such as ScvO2 and Lactate - alone and in combination - might be useful to estimate Cardiac Index (CI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/06/2012 (Project 5384/12), 30/12/2011 (Project 501/11), 18/04/2017 (Project 3049 /11s), Ethikkommission der Technischen Universität München (Fakultät für Medizin. Ismaningerstrasse 22. D-81675 München, Tel: +49 (0)89 4140 7737; Email: ethikkommission@mri.tum.de), ref: 3049/11s; 5101/11; 5384/12

Study design
Study bundle with more than 10 sub-studies (BOSTON-I; BOSTON-II; BOSTON-III etc.).
All studies have in common that Goldstandard Cardiac Index and Body core temperature (BCT) is measured with transpulmonary thermodilution (PiCCO; Pulsion Medical Systems SE; Feldkirchen; Germany), and Body Surface temperature is measured with a non-contact infrared Thermometer (Thermofocus or Visoofocus; Tecnimed; Varese; Italy). In Addition other less or non-invasive devices to assess CI (e.g. FloTrac; Edwards Lifesciences; Irvine; USA; ProAqt; Pulsion Medical Systems SE; Feldkirchen, Germany; ClearSight; Edwards Lifesciences; Irvine; USA); are compared with CI derived from thermodilution (PiCCO: CI_TD) and CI derived from BST (CI_BST).

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Critical care patients at risk of shock

Interventions
The main intervention is to observe the association of body surface temperatures measured with a non-contact infrared Thermometer (Thermofocus) with body core temperatures measured with a Thermistor-equipped arterial catheter (PiCCO; Pulsion Medical Systems SE; Feldkirchen; Germany), with a Thermistor-tipped urinary catheter (Urosid Sensor 400; ASID BONZ; Herrenberg; Germany) and an ear Thermometer (ThermoScan; Braun; Melsungen; Germany) and with cardiac index derived from transpulmonary thermodilution (PiCCO; Pulsion Medical Systems SE; Feldkirchen; Germany) and less invasive devices to estimate cardiac index. Measurements and comparisons are performed between 2 and 8 times within one and five days.

Intervention Type
Other

Primary outcome measure
1. Body surface temperatures measured with a non-contact infrared Thermometer (Thermofocus)
2. Body core temperatures measured with a Thermistor-equipped arterial catheter (PiCCO; Pulsion Medical Systems SE; Feldkirchen; Germany), with a Thermistor-tipped urinary catheter (Urosid Sensor 400; ASID BONZ; Herrenberg; Germany) and an ear Thermometer (ThermoScan; Braun; Melsungen; Germany)
3. Cardiac index derived from transpulmonary thermodilution (PiCCO; Pulsion Medical Systems SE; Feldkirchen; Germany) and less invasive devices (e.g. FloTrac, ProAqt, ClearSight)
Body surface temperatures, body core temperatures and cardiac index are measured between 2 and 8 times within one and five days. The typical schedule for comparisons of estimates of cardiac index based on body surface temperatures or less invasive devices with gold standard measurement of cardiac index with the PiCCO device is based on eight measurements within 24 h (0:00 h; 0:30 h; 2:00 h; 4:30 h; 8:00 h; 20:00 h; 23:30 h; 24:00 h).

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/07/2009

Completion date
21/12/2021

Eligibility

Key inclusion criteria
Haemodynamic monitoring with transpulmonary thermodilution (PiCCO) according to the local standard and irrespective of the study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Cumulative number: n=500; per sub-study n=30 to n=80

Key exclusion criteria
Contra-indications for PiCCO-monitoring

Date of first enrolment
25/08/2009

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
Germany

Study participating centre
Technische Universität München
Medizinische Klinik und Poliklinik II
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Sponsor information

Organisation
Technische Universität München

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Sponsor type
University/education

ROR
https://ror.org/02kkvpp62

Funder(s)

Funder type
University/education

Funder Name

Results and Publications

Publication and dissemination plan

1. All results will be submitted to peer-reviewed journals
2 The results of BOSTON-I and BOSTON-II will be submitted in July 2019
3. Preliminary results of BOSTON-III to BOSTON-VII have been presented on international critical care congresses (ESICM; SCCM; ISICEM)

Intention to publish date

30/09/2019

Individual participant data (IPD) sharing plan

Due to ethical and legal restrictions imposed by Ethikkommission der Fakultät für Medizin der Technischen Universität München, confidential data are available upon request. To receive anonymized data readers are welcome to contact the corresponding author (Prof. Dr. Wolfgang Huber, II. Medizinische Klinik und Poliklinik, Klinikum rechts der Isar der Technischen Universität München, Ismaninger Strasse 22, D-81675 München, Germany; Wolfgang.Huber@tum.de). Data will be available after final publication for up to 5 years.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article	BOSTON-I-study	14/11/2019	21/02/2024	Yes	No