The effect of Body temperature regulation on host response in patients with Septic shock (A sub-study of the CASS study)

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Primary: To determine the effects of MIH on circulatory, inflammatory and metabolic aspects of host response to sepsis.Secondary: To determine if MIH prevents and/or decreases the severity of ICU-AW in septic shock.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Body temperature conditions
Study type	Observational invasive

Summary

ID

NL-OMON44527

Source
ToetsingOnline

Brief title
Body temperature regulation and host response

Condition

- Body temperature conditions
- Bacterial infectious disorders

Synonym
blood poisening, Septic shock

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: LEICA

Intervention

Keyword: host, hypothermia, response

Outcome measures

Primary outcome

Metabolism: Mitochondrial 02 consumption

Circulation: Sublingual microcirculatory flow index

Inflammation: Total amount of circulating microparticles

Lung injury: total protein and inflammation markers in NBL

Secondary outcome

ICU-AW: MRC score

Study description

Background summary

In the CASS study, the main focus lies on clinical parameters of organ dysfunction in septic shock patients treated with mild induced hypothermia (MIH). This is also the case in other studies researching body temperature regulation and sepsis in humans. However, unravelling the mechanistic pathways of mild induced hypothermia in humans is imperative in our understanding the potential therapeutic effects of MIH. This substudy of the CASS study aims to elucidate the effects of regulating body temperature on circulatory, inflammatory and metabolic aspects of host response to sepsis. These changes also form the pathophysiologic basis for the development of intensive care-acquired weakness (ICU-AW).

Study objective

Primary: To determine the effects of MIH on circulatory, inflammatory and metabolic aspects of host response to sepsis.

Secondary: To determine if MIH prevents and/or decreases the severity of ICU-AW in septic shock.

Study design

Randomized, single-blinded multicenter trial.
Patients included in the CASS study will be asked to participate in this substudy. The patients will be subjected to several extra measurments.
For the purpose of whole blood stimulation, healthy controls will be recruited.

Study burden and risks

For patients there are no direct benefits for participation in this study. The results of this study will result in a better understanding of the therapeutic effects of MIH. The additional burden and risks for patients participating in the substudies is minimal. In addition to routine blood samples we will to take an extra 28 ml of blood on study day 1 and 28 on study day 3 (or at discharge). These samples will be taken from arterial lines that are already in place causing no additional discomfort to the patient. NBL's are frequently done at our ICU and are part of standard airway care. The risk of this procedure is small .The clinical measurements we will perform are minimally invasive, not painful and are partially done while the patient is sedated minimizing patient burden. Muscle strength scoring is standard of care in our department and will be done once the patient is awake.
A total amount of 24 ml of blood will be taken from each healthy individual.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients who have been included in the CASS trial
Healthy volunteers: 18 years or older

Exclusion criteria

- No informed consent for the substudy
- A platelet count < 10 x 10^9 /L
- Known mitochondrial disease
- Patient received platelet transfusion less than 6 hours before blood samples are taken

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2014
Enrollment:	78
Type:	Actual

Ethics review

Approved WMO Date:	21-08-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-10-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL49182.018.14