Can Mild Induced Hypothermia reduce mortality in septic shock patients at the Intensive Care Unit?
A randomized, single-blinded, multicenter study. The cooling and surviving septic shock study

Published: 21-08-2014
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To investigate whether cooling to 33 °C for 24 hours in septic shock reduces mortality in intensive care patients.

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

Summary

ID

NL-OMON44609

Source
ToetsingOnline

Brief title
CASS study

Condition

- Body temperature conditions
- Bacterial infectious disorders

Synonym
blood poisening, Sepsis

Research involving

Human

Sponsors and support

Primary sponsor: CHIP HIV copenhagen
Source(s) of monetary or material Support: Deense Research fondsen,Lundbeck Foundation,The Danish Freemason society,Tryg Foundation

Intervention

Keyword: Hypothermia, Sepsis, Shock, Therapy

Outcome measures

Primary outcome

All cause mortality at 30 days

Secondary outcome

1. Duration of cardiac/septic shock

2. Respiratory failure

3. Renal failure

4. Cerebral dysfunction

5. Liver failure

6. Coagulation disorders

7. Infection parameters

8. Days without organ failure up to day 30

Study description

Background summary

Septic shock patients have approximately 50% risk of death, usually related to the development of multiple organ failure. There is evidence mild induced hypothermia (MIH) inhibits the inflammatory response, thereby limiting organ failure in ischemia and reperfusion injury, including cardiac arrest, stroke,

and neonatal hypoxia. Hypothermia is also applied peri-operatively to limit ischemia reperfusion injury.
Several experimental sepsis animal models have shown improved survival when treated with induced hypothermia. In clinical studies, patients with septic shock cooled to normothermia had a reduced need for inotropic substances compared to febrile patients and hypothermia improved gas exchange with a trend towards better survival compared to group that did not receive hypothermia.

Study objective

To investigate whether cooling to 33 °C for 24 hours in septic shock reduces mortality in intensive care patients.

Study design

Randomized, single-blinded multicenter trial.

560 ICU-patients are included in the study. All patients will receive the standardized and recommended diagnostics and treatment used at the specific ICU they are admitted to (Standard of care).
Furthermore, the patients are randomized to:
1. Standard-of-care: Control arm. Or 2. Mild induced hypothermia 33 °C

Intervention

Cooling to 33°C for 24 hours. The patient is subsequently rewarmed and kept normothermic (36 °C - 38 °C) for 72 hours from start of randomization. After 72 hours, the intervention stops.

Study burden and risks

Potential benefits to the patient are decreased occurrence of organ failure, faster shock reversal, shortened time on the ICU and lower mortality. Group relatedness: improved treatment of sepsis. Risks associated with MIH are potential coagulopathy, electrolyte disorders and arrhythmia. However, our department has extensive experience with cooling patients (with cardiac arrest), and managing the potential complications of this treatment. Moreover, extensive coagulation measurements were performed in the first 50 patients included in this study, showing no deterioration of coagulation status in patients in the MIH group.

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

- Aged 50 years or older.
- Severe sepsis/septic shock
- Admitted to the participating intensive care units (ICU)
- (Indication for) mechanical ventilation
- Possibility of inclusion within 6 hours after septic shock/severe sepsis is diagnosed in the ICU.
- Expected stay in the ICU of more than 24 hours

Exclusion criteria

- Pregnant or breast feeding
- Bleeding disorder and/or uncontrollable bleeding and /or surgery within the last 24 hours or expected surgery in the coming 12 hours
- Persons who are detained under the Act on the use of coercion in psychiatry

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2014
Enrollment:	52
Type:	Actual

Ethics review

Approved WMO Date:	21-08-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-03-2015
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
ClinicalTrials.gov	NCT01455116
CCMO	NL49105.018.14