Effect of mild therapeutic hypothermia in post cardiac arrest patients on inflammatory response

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We want to describe in detail the MTH-induced changes in pro- and anti-inflammatory markers in patients after CA. We further aim to evaluate the relation between neurological outcome and levels of pro- and anti-inflammatory markers.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON39281

Source
ToetsingOnline

Brief title
EMIR

Condition

- Heart failures

Synonym
brain damage, cardiac arrest

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac arrest, Inflammatory markers, Mild therapeutic hypothermia, Predictive value

Outcome measures

Primary outcome

Determine whether minor variations in the expression of systemic pro- and anti-inflammatory markers in post-CA patients during treatment with hypothermia result in better neurological outcome compared to patients showing large variations.

Secondary outcome

- Does the expression of pro- and anti-inflammatory markers relate to mechanical ventilation days, length of stay at the ICU and survival of the patients?

- Is there an association between the expression of pro- and anti-inflammatory markers and speed of cooling and re-warming?

- Is there an association between the expression of pro- and anti-inflammatory markers and temperature stability during the maintenance phase of MTH?

- Is there a relation between hypoperfusion (measured with NIRS) and markers of inflammation before, during and after induction of MTH in post-CA patients

Study description

Background summary

Mild therapeutic hypothermia (MTH) has been shown to improve survival and neurological outcome in patients successfully resuscitated after cardiac arrest (CA). While MTH is standard therapy worldwide, there is no proof of the optimal

timing and speed of cooling and re-warming. The mechanisms underlying the beneficial effects of MTH are multiple and can affect various steps in the cascade of ischemia and reperfusion. In post-CA resuscitated patients an early systemic inflammatory response emerges, characterized by increased markers of inflammation, which may last hours to several days. Animal models for brain ischemia and cell culture experiments have shown that hypothermia decreases the production of inflammatory cytokines. Furthermore, in a small study of ten post-CA patients hypothermia seems to shift the inflammatory balance mainly during the re-warming phase. Hypothermia induced effects on the inflammatory balance in post-CA patients are still largely unknown. Therefore, in this study we aim to observe how MTH modulates the systemic inflammatory response after CA and whether it relates to patient*s outcome and longitudinal measurements of tissue perfusion.

Study objective

We want to describe in detail the MTH-induced changes in pro- and anti-inflammatory markers in patients after CA. We further aim to evaluate the relation between neurological outcome and levels of pro- and anti-inflammatory markers.

Study design

Prospective observational single centre study at the ICU.

Study burden and risks

This study is observational and does not carry additional risks for the included patients. Blood sampling will be done from an existing intra-arterial catheter, which is present as standard care in all cardiac arrest patients admitted to the ICU, and will not exceed 5 times 9.5ml (total: 47.5ml). The non-invasive cerebral tissue hemoglobin oxygenation measurements are performed with a probe that is integrated in a forehead patch. These measurements are already performed during cardiothoracic procedures in order to monitor cerebral tissue perfusion, and do not add up to patient discomfort.

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

- age >=18 years
- post cardiac arrest with spontaneous return of circulation
- undergoing mild therapeutic hypothermia
- admittance to the intensive care
- written informed/deferred consent

Exclusion criteria

-pregnancy
-severe traumatic brain injury
-cardiac arrest due to submersion
-infection already present before collapse
-moribund patients

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-01-2013
Enrollment:	51
Type:	Actual

Ethics review

Approved WMO Date:	19-11-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-04-2013
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	NL39943.029.12