Disturbances in microvascular perfused boundary region and plasma levels of syndecan-1 and heparan sulfate in cardiopulmonary resuscitated patients during re-warming phase of therapeutic hypothermia treatment.

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Determine whether and to what extent changes in microvascular perfused boundary region and syndecan-1 and heparan sulfate plasma levels, as measures for glycocalyx damage, occur in survivors and non-survivors of CA during the re-warming phase of...

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

Summary

ID

NL-OMON38597

Source
ToetsingOnline

Brief title
Microvasculature during therapeutic hypothermia (VASCA)

Condition

- Heart failures

Synonym
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, Glycocalyx, Therapeutic hypothermia

Outcome measures

Primary outcome

Determine whether and to what extent changes in microvascular PBR, as measure for glycocalyx damage, occur in survivors and non-survivors of CA during the re-warming phase of therapeutic hypothermia treatment.

Secondary outcome

- Determine whether and to what extent changes in syndecan-1 and heparan sulfate plasma levels, as measure for glycocalyx damage, occur in survivors and non-survivors of CA during the re-warming phase of therapeutic hypothermia treatment.
- Determine the association of syndecan-1 and heparan sulfate plasma levels with the PBR in post-CA patients during the re-warming phase of therapeutic hypothermia treatment.
- Determine whether and to what extent changes in microcirculatory perfused vessel density (PVD) and mean flow index (MFI) occur in survivors and non-survivors of CA during the re-warming phase of therapeutic hypothermia treatment.

Study description

Background summary

Despite the appropriateness of mild therapeutic hypothermia to increase survival and improve neurological outcome in patients after cardiac arrest (CA), the mortality rate remains high in post-CA patients and full recovery in survivors is still as low as 6-23%. The episode of CA with subsequent cardiopulmonary resuscitation and return of spontaneous circulation represents the process of global ischemia followed by reperfusion, which generates a systemic inflammatory response. Besides other actions therapeutic hypothermia limits this inflammatory response. However, after the period of therapeutic hypothermia of 32-34oC the patient will be re-warmed to a normal body temperature. A recent study showed in ten post-CA patients treated with mild therapeutic hypothermia, a pro-inflammatory effect only during the re-warming phase and not during the cooling phase. To what extent this inflammatory response during the re-warming phase affects the microvasculature and changes the integrity of the vascular wall is unknown. The endothelial glycocalyx has been proved to be an important modulator of vascular permeability, coagulation, leukocyte adhesion and inflammation, and functions as an endothelial barrier. Glycocalyx function can be determined indirectly by measurement of components of the glycocalyx (syndecan-1 and heparan sulfate) in plasma. With the recent introduction of a novel technique for evaluation of sublingual microvascular changes it has become possible to measure glycocalyx dimensions in patients. This study investigates associations between biomarkers of glycocalyx damage and mortality in post-CA patients during re-warming phase of therapeutic hypothermia, hypothesizing that in non-survivors of CA glycocalyx damage will be more pronounced during re-warming compared to survivors.

Study objective

Determine whether and to what extent changes in microvascular perfused boundary region and syndecan-1 and heparan sulfate plasma levels, as measures for glycocalyx damage, occur in survivors and non-survivors of CA during the re-warming phase of therapeutic hypothermia treatment.

Study design

Prospective observational single center study at the ICU

Study burden and risks

This study is observational and does not carry additional risks or burden for the included patients. Blood sampling will be done from an existing catheter located in an artery, which is present as standard care in all post-CA patients

admitted to the ICU, and will not exceed 6 times 4.5ml (total: 27ml). Sublingual measurement of the microcirculation is non-invasive and not longer than 3 minutes per measurement. All patients treated with therapeutic hypothermia at the ICU are sedated, therefore these measurements do not add up to patient discomfort. There are no benefits from the present study for the patient.

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
* out-of hospital cardiac arrest with spontaneous return of circulation
* undergoing mild therapeutic hypothermia
* admittance to the intensive care unit

* written informed/deferred consent

Exclusion criteria

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

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-11-2013
Enrollment:	39
Type:	Actual

Ethics review

Approved WMO

Date:	30-10-2013
Application type:	First submission
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	NL45946.029.13