Hypothermia induced changes in organ perfusion in patients after cardiac arrest

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON35322

Source
ToetsingOnline

Brief title
Viscosity during hypothermia

Condition

- Other condition
- Neurological disorders NEC

Synonym
cardiac arrest, organ blood flow

Health condition

bloedruk en orgaandoorbloeding na hartstilstand

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bloodflow, Hypothermia, Perfusion, Viscosity

Outcome measures

Primary outcome

Main study endpoint is the change in blood viscosity in time during hypothermia and subsequent rewarming.

Secondary outcome

Secondary study parameters are

- Hemodynamic changes, such as heart rate, blood pressure, cardiac output, central venous pressure, pulse pressure variation (PPV), stroke volume, stroke volume variation (SVV), systemic vascular resistance (SVR), global end-diastolic volume, intrathoracic blood volume, and extravascular lung water during hypothermia and rewarming.
- Changes in parameters of cardiac compliance during hypothermia and rewarming.
- Changes in cerebral, renal and splanchnic blood flow during hypothermia and rewarming.
- Changes in cerebral autoregulation during hypothermia and rewarming.
- Effect of fluid resuscitation on hemodynamic parameters and whole blood viscosity during hypothermia and rewarming.

Study description

Background summary

The prognosis of patients after cardiac arrest is poor. Hypotension in the postresuscitation phase is associated with an increased mortality and a greater than 3fold increased odds of in-hospital death. Primary aim of the ICU treatment after cardiac arrest is prevention of secondary organ damage by ensuring adequate blood flow and oxygenation of all organs. Little is known about the effects of hypothermia on blood pressure and organ blood flow. Organ blood flow is dependent on blood flow, perfusion pressure and viscosity of whole blood. Hypothermia may change the flow properties of blood, thus influencing oxygenation of organs. Most organs are protected against changes in organ blood flow through the mechanism of autoregulation. Autoregulation may be disturbed after cardiac arrest. The effects of hypothermia on autoregulation is unknown

Study objective

Main objective is to study changes in in vivo blood viscosity during mild therapeutic hypothermia and rewarming in patients after cardiac arrest.

Secondary objectives are to study the effects of cooling and rewarming on
-Hemodynamic parameters
-changes in cardiac compliance
- Fluid resuscitation
-cerebral autoregulation
-blood flow through organs such as brain, gastrointestinal tract and kidney

Study design

Observational study.

Study burden and risks

The study will be performed in incapacitated patients, since hypothermia is only indicated in comatose patients that are (by definition) at least temporarily incapacitated. The study is largely observational in nature, using measurements and techniques that are routinely used in these critically ill patients. The study will be completed during the stay in the ICU, and does not require additional visits to the hospital. Measurement of organ blood flow, such as cerebral and renal blood flow is done with a non-invasive technique, without risk or burden to the patient. A gastric tonometry catheter will be used instead of a standard gastric feeding tube. This tube has the same properties as standard tubes and does not require replacement by a standard

tube after completion of the study. The central venous catheter used for in vivo measurement of viscosity has the same properties compared to standard venous (Arrow®) catheters. Insertion and use of this catheter will not lead to additional risks compared to a standard catheter. After completion of the experiments this catheter will be used as a standard central venous catheter. Fluid resuscitation in patients after cardiac arrest is part of standard care. Before and after administration of a fluid bolus, additional hemodynamic and viscosity measurements will be performed, mostly as part of routine intensive care. Taken together, the risk and burden associated with participation to this study are minimal. Participation will not directly be beneficial for the individual patient, but will enable the investigators to learn more about the effects of hypothermia on hemodynamic characteristics and organ perfusion.

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

- Informed consent
- Age >= 18 years
- Out of hospital cardiac arrest
- Initial rhythm on arrival of the ambulance ventricular fibrillation or non-perfusion ventricular tachycardia or a presumed cardiac origin of the arrest
- Glasgow coma score upon arrival at the hospital of 8 or less
- Indication for mild therapeutic hypothermia

Exclusion criteria

- Comatose state before cardiac arrest or known neurological disease
- Cardiogenic shock, defined as mean arterial pressure less than 60 mmHg and/or urine production < 0.5 ml/kg bodyweight/hour, despite use of inotropic agents
- Hypoxemia, defined as oxygen saturation in arterial blood < 85%
- Chronic renal failure (creatinine > 200 µmol/ml), chronic liver failure
- Pregnancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	13-04-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL23118.091.09