Multi-Center Observational study to assess optimal ECMO settings during the first hours of Extra-Corporeal Cardiopulmonary Resuscitation.

Published: 21-11-2017
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Primary Objective: To prospectively identify parameters correlated with Cerebral Performance Category (CPC)* * 2 at hospital discharge. Secondary Objective(s): - Parameters correlated with a CPC*1 * 2, 6 months after arrest- Parameters correlated...

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

Summary

ID

NL-OMON50088

Source
ToetsingOnline

Brief title
Observational study to assess optimal ECPR settings after resuscitation

Condition

- Cardiac arrhythmias
- Vascular therapeutic procedures

Synonym
Cardiac arrest, Reperfusion injury after extracorporeal cardiopulmonary resuscitation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Nonin

Intervention

Keyword: Cardio-Pulmonary resuscitation, Extra-Corporeal CardioPulmonary Resuscitation, ischemia-reperfusion injury

Outcome measures

Primary outcome

CPC* 2 at hospital discharge

Secondary outcome

- CPC*1 * 2, 6 months after arrest

- GCS>13 at day 28

- GCS > 13 at any time

- 28 days Mortality

- Hospital survival

Study description

Background summary

Veno-arterial extracorporeal membrane oxygenation (vaECMO) during cardiopulmonary resuscitation (ECPR) might improve outcome after cardiac arrest. Two independent propensity matched observational studies show that survival with good neurological outcome is more than doubled during ECPR compared to conventional CPR: (10% vs 23% and 5% vs 23%). Eight observational studies entered a meta-analysis and showed a benefit ratio of 3.15 for good neurologic outcome one year after arrest, in favour of ECPR versus conventional resuscitation. Due to the many observational studies, the European resuscitation council decided that ECPR could be considered during refractory cardiac arrest.
However, it is well established that reperfusion injury of the brain can cause microvascular and endothelial dysfunction, leading to cellular

necrosis and apoptosis. Factors that may play a role are for example the rate that PaCO2 decreases or PaO2 increases directly after arrest; in children for example, a PaCO2 difference last pre-ECMO - first post-ECMO > 25 mmHg significantly predicted for mortality. Furthermore, Kredel et al. demonstrated in veno-venous ECMO that rapid decrease in PaCO2 resulted in a marked decrease of cerebral tissue oxygenation.
While performing ECPR, following the European guidelines, it is yet unknown how to adjust the ECMO settings in order to minimize ischemia-reperfusion injury of the brain. In this study, we want to elaborate on the optimal ECMO settings in the first three hours after initiation of ECPR. In order to develop a reperfusion strategy to minimise ischemia-reperfusion injury of the brain during ECPR, we plan to perform an international observational multi-center study to determine relevant factors affecting neurological outcome after ECPR.

Study objective

Primary Objective: To prospectively identify parameters correlated with Cerebral Performance Category (CPC)* * 2 at hospital discharge.

Secondary Objective(s):
- Parameters correlated with a CPC*1 * 2, 6 months after arrest
- Parameters correlated with a GCS>13 at day 28
- Parameters correlated with a GCS > 13 at any time
- Parameters correlated to 28 days Mortality
- Parameters correlated to Hospital survival

Study design

This is a multi-centre prospective observational cohort study, for a duration of 1,5 year and will contain patients receiving ECPR during cardiac arrest. Patients are followed until 6 months after arrest.

Study burden and risks

There are minimal burden expected to the patient: theoretical it is possible that the adhesive sensors cause irritation to the skin. The extra blooddrawings will be perfomed from existing indwelling cannulas. The patient will not receive extra punctures for study purposes. In the first hour, 4 bloodgas analysis will be performed (1.5 ml each), and the subsequent 2 hours one bloodgas analysis (1.5 ml each) each 30 min. These procedures will not cause any discomfort to the patients, these blooddrawings will be performed from an existing indwelling catheter. 6 months after arrest, patients will receive a telephone call by their attending doctor, asking 7 yes/no questions for assessing their functional status. NSE and cardiac markers (Trop T, CK, CM-mb)

will be determined from routine blood drawings.

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

- Witnessed cardiac arrest or signs of life during CPR (such as gasping or movement)
- Age>18 and < 70 years
- Duration of low-flow < 60 min before decision to proceed with ECPR
- High quality CPR (defined as CO2et>10 mmHg) provided for a minimum of 15 minutes without ROSC
- Cerebral oxymetry monitoring initiated during CPR preceding ECPR

Exclusion criteria

- Patients with a GCS<15 before CPR.
- Known pre-arrest cerebral performance category CPC***3
- Unwitnessed collapse
- Suspected or confirmed pregnancy
- ROSC within 5 minutes of ACLS performed by EMS team
- Conscious patient
- Known bleeding diathesis or suspected or confirmed acute or recent intracranial bleeding
- Suspected or confirmed acute stroke
- Known severe chronic organ dysfunction or other limitations to therapy
- *Do not resuscitate* order or other circumstances that make 180 day survival unlikely

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-01-2019
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Date:	22-11-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	04-03-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-10-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL60632.078.17