The microcirculation in children treated with extracorporeal membrane oxygenation;
an observational longitudinal study

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To study whether microcirculatory perfusion is improved by ECMO. Perfusion will be studied before & after ECMO start, during ECMO weaning and before & after ECMO stop. To study the precictive value of perfusion and its correlation with the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Red blood cell disorders
Study type	Observational non invasive

Summary

ID

NL-OMON34390

Source
ToetsingOnline

Brief title
Microcirculatory changes during ECMO

Condition

- Red blood cell disorders
- Cardiac disorders, signs and symptoms NEC
- Neonatal respiratory disorders

Synonym
respiratory and/or cardiac failure

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Children, Extracorporeal membrane oxygenation, Microcirculation

Outcome measures

Primary outcome

The main study endpoint is (*) microcirculatory perfusion (defined by the parameters PVD & MFI) at 2h and at 24h after ECMO cannulation. This will be evaluated for VA-ECMO and VV-ECMO patients separately.

Secondary outcome

- (*) Microcirculatory perfusion (defined by the parameters PVD & MFI) at D1-D6 in VA-ECMO patients as compared to (*) microcirculatory perfusion at D1-D6 in VV-ECMO patients.
- (*) Microcirculatory perfusion (defined by the parameters PVD & MFI) at 12h before and at 12h and 24h after ECMO decannulation. This will be evaluated for VA-ECMO and VV-ECMO patients separately.
- The incidence of mortality within the first 28 days after (decannulation of) ECMO
- (*) Microcirculatory perfusion (defined by the parameters PVD & MFI) in VA-ECMO patients during ECMO flow class I (flow * 50 ml/kg/min), ECMO flow class II (50 ml/kg/min < flow * 150 ml/kg/min) and ECMO flow class III (ECMO flow * 150 ml/kg/min).
- (*) Microcirculatory perfusion (defined by the parameters PVD & MFI) in

VA-ECMO and VV-ECMO patients separately in correlation to other macro- and microcirculatory parameters (in order of importance: vasopressor score, ECMO flow, lactate, skin temperature, pH, core body temperature, Hb, Ht, MAP, SvO2, pre- and postductal saturation and HF).

- (*) Microcirculatory perfusion (defined by the parameters PVD & MFI) and tissue oxygenation (defined by the parameters rSO2 & FOE) 2 and 24 hours after RBC transfusion. This will be evaluated for VA-ECMO, VV-ECMO and postsurgical patients separately.

Study description

Background summary

Children with therapy resistant (cardio)respiratory failure are eligible for extracorporeal membrane oxygenation (ECMO). In essence, ECMO is intended to improve tissue perfusion and oxygenation at the cellular level thereby decreasing mortality. After ECMO initiation, macrocirculatory and respiratory parameters improve instantly. However, ECMO initiation is also associated with detrimental microcirculatory factors such as severe inflammatory response syndrome, non-pulsatile blood flow and possibly, transfusions with stored red blood cells. As there is evidence to suspect a discrepancy between macro- and microcirculation, monitoring of microcirculatory perfusion is important. Moreover, there is a diagnostic gap regarding tissue perfusion. Monitoring microcirculatory perfusion before during and after ECMO might prove to be useful not only to evaluate the efficacy of ECMO, but might help to optimize ECMO treatment as well. Limited studies have been performed using non-invasive functional biomarkers to study the microcirculation in critically ill children and ECMO patients in particular.

Study objective

To study whether microcirculatory perfusion is improved by ECMO. Perfusion will be studied before & after ECMO start, during ECMO weaning and before & after ECMO stop. To study the precictive value of perfusion and its correlation with the macrocirculation. To study the microcirculatory effects of RBC transfusion during ECMO.

Study design

Investigator initiated, single center, observational, prospective cohort study

Study burden and risks

Subjects will have no direct benefits of participating in this study. We aim to assess the objectives using a non-invasive, functional biomarker tool called Sidestream Dark Field Imaging (SDF). No adverse events have been reported using SDF. The expected burden for participants is very low, as the study procedure is non-invasive and no radiation or other known damaging factors are involved. Total study procedure will take maximally 5 minutes for each measurement. The only possible burden could be that measurements need to be performed before, during and after ECMO and that some minor manipulation may be required to obtain qualitatively good measurements. Standard, protocolized therapy will be monitored as this is an observational study. Other than SDF, patients will not be exposed to any additional medical or diagnostic procedures, nor will medical or diagnostic procedures be postponed due to SDF measurements.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Group 1 & 2:
-Patients admitted to the (neonatal and/or pediatric) IC of Erasmus MC-Sophia, in need of ECMO either due to pathology for which they are primarily admitted or due to secondary pathology which originates during their admittance in the IC.
- Parental informed consent before ECMO obtained by using the short patient information letter (PIF no. 1; see Ch. 8.2 research protocol) and parental informed consent obtained within 24h after ECMO start obtained by using the regular PIF (PIF no. 2; see Ch. 8.2 research protocol)
-Patients in group 2 will be matched 1 on 1 to patients in group 1 for gender and age (± 6 months);Group 3:
- Term patients admitted to the IC of Erasmus MC-Sophia in need of RBC transfusion after surgery (e.g. patients after craniofacial surgery, patients after cardiac surgery)
- Parental informed consent
- Patients in group 3 will be matched 1 on 1 to patients in group 1 for gender and age (± 1 month)

Exclusion criteria

Group 1 & 2:
- Age * 18 years
- Rapid response ECMO outside the IC of Erasmus MC-Sophia
- Transfer on ECMO to the IC of Erasmus MC-Sophia (including the dept. of thoracic surgery of Erasmus MC-Sophia)
- Unsuccessful cannulation and/or inability to generate sufficient blood flow
- ECMO exclusion criteria (e.g. weight < 2kg., irreversible pathology);Group 3:
- Preterm infants
- Age * 18 years
- RBC transfusion by irradiated blood cell products
- RBC transfusion of blood cell savers
- Term patients diagnosed with malignancy (hematologic and/or solid organ)
- Term patients diagnosed with hemoglobinopathy of any kind
- Term patients diagnosed with bone marrow disease of any kind
- Cardiopulmonary resuscitation and subsequent therapeutic hypothermia
- Severe pathology which imply abstinence of therapy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2011
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	15-12-2010
Application type:	First submission
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	NL34017.078.10