ECMO in newborn infants: circulatory changes in relation to venovenous and venoarterial bypass. Implications for periferal organ circulation

Published: 14-01-2008
Last updated: 08-05-2024

I. Evaluation of changes in pulmonary and systemic circulation during VV- ECMO treatment and difference between V-V- and V-A ECMOII. Evaluation of changes in cerebral, renal and mesenterial organ perfusion during ECMO treatment and difference...

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

Summary

ID

NL-OMON30856

Source
ToetsingOnline

Brief title
Circulatory Changes during VV- and VA ECMO

Condition

- Other condition

Synonym
persistent pulmonary hypertension of the neonate

Health condition

systemische en perifere circulatie

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: op dit moment nog geen financering; aanvraag bij hartstichting is gepland

Intervention

Keyword: organ circulation, PPHN, VA- ECMO, VV- ECMO

Outcome measures

Primary outcome

Assessment of:

Hemodynamic changes in pulmonary and systemic circulation

Secondary outcome

1. Changes in cerebral, renal and mesenterial blood flow

2. Renal function in relation to hemodynamic changes

3. BNP in relation to fluid homeostasis

Study description

Background summary

Persistent pulmonary hypertension of the newborn (PPHN) is a life threatening disease with a high mortality rate. Extracorporeal Membrane Oxygenation (ECMO) with veno-arterial (V-A) or veno-venous (V-V) cannulation can provide a last treatment option. Differences in circulatory changes between V-A and V-V ECMO concerning the course of PPHN and organ perfusion are not known. Independent of the underlying disease, courses of ECMO runs (with both systems) may differ a lot. Impairment of renal function and oedema is frequently seen. Mechanisms that may play a role are not well understood yet. A better understanding of hemodynamic changes in systemic and pulmonary circulation during treatment of PPHN with ECMO as well as consecutive changes in organ perfusion and function will help to develop more rationalistic treatment strategies to accelerate the recovery to a normal neonatal circulation and shorten ECMO treatment. This will

reveal positive effects for patients as well as favourable effects on economic aspects for this very intensive treatment.

Study objective

I. Evaluation of changes in pulmonary and systemic circulation during VV- ECMO treatment and difference between V-V- and V-A ECMO
II. Evaluation of changes in cerebral, renal and mesenterial organ perfusion during ECMO treatment and difference between V-V- and V-A ECMO
III. Evaluation of hemodynamic changes during ECMO treatment in relation to renal function and difference between V-V- and V-A ECMO
IV. Evaluation of BNP as diagnostic parameter regarding fluid homeostasis during ECMO treatment and difference between V-V- and V-A ECMO

Study design

The study will have an observational character including two cohorts. The first cohort consists of a group of patients that have been evaluated in a former study, exclusively treated with V-A ECMO. The second cohort of patients will include prospectively patients receiving V-V as well as V-A ECMO. A study period of 2 and a half years is aimed for inclusion of a sufficient number of patients. All consecutively patients admitted for ECMO treatment to the department of neonatology of the RUNMC will be evaluated for inclusion into the study.

Intervention: All patients will receive the standard treatment following the ECMO protocol of the department. According to the study protocol patients will be evaluated at standard intervals starting directly before cannulation for ECMO until 24 hours after decannulation. Evaluation will consist of registration of hemodynamic variables and parameters for organ perfusion using echocardiography and Doppler sonography, blood and urine sampling and registration of physiological and patient data.

Study burden and risks

Adverse events that may be expected are discomfort for the patient during echocardiography and Doppler sonography and anemia caused by blood losses because of frequent determination of blood samples. Since all patients are under continuous sedation and analgesia during ECMO treatment discomfort is limited to a minimum during investigational procedures. Discomfort caused by repetitive measurements has not been a problem during the previous study.

Anemia during ECMO procedure will be prevented by blood sampling in combination with routine blood samples in order to control oxygenation and ventilation, milieu interieur and concentration of haemoglobin and hematocrit. The haemoglobin concentration is kept stable above eight mmol/l with transfusions

of packed cells according to standard ECMO protocol for all patients. All patients are equipped with arterial lines and urine catheters which facilitates blood and urine sampling without causing discomfort.

Newborn infants belong to the group of minor and incapacitated subjects nevertheless it is necessary to perform this study in this specific patient group because the pathology of PPHN is age related to the period of transition from fetal to neonatal circulation. Organ function and circulatory changes in an adult patient group are not comparable to the neonatal physiology.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

newborn infants with gestational age > 34 weeks and reversible causes of PPHN and indication for ECMO treatment

Exclusion criteria

multiple congenital malformations
congenital heart disease
congenital hernia diafragmatica
infants post cardiosurgery

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

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	NL18216.091.07