Echocardiographic-derived parameters of heart function in neonates undergoing extracorporeal membrane oxygenation

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To describe serial changes in diastolic and systolic myocardial performance by comprehensive echocardiographic assessment in neonates prior to, during, and after ECMO treatment and relate this to the course of PPHN.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON46379

Source
ToetsingOnline

Brief title
ECHocardiography in neonates undergoing ECMO (ECHMO)

Condition

- Other condition
- Neonatal and perinatal conditions
- Vascular hypertensive disorders

Synonym
Extracorporeal membrane oxygenation (ECMO), heart-lung machine

Health condition

ECMO bij neonaten

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Bijdrage door bedrijf (Maquet),Maguet

Intervention

Keyword: Echocardiography, ECMO, Heart function, Neonate

Outcome measures

Primary outcome

The main study parameters are the generally used clinical and study related echocardiographic parameters of heart function arranged by left ventricle and right ventricle during systole and diastole using conventional, tissue Doppler, and deformation echocardiographic technologies. These parameters will be measured prior to, during, and after ECMO therapy.

The following parameters will be measured:

Left ventricle

Left ventricular dimensions: Left ventricular ejection fraction (LVEF)

Color-pooled Doppler (pulse wave): Mitral valve peak early diastolic flow velocity (E), peak atrial flow velocity (A), right ventricular ejection time (RVET).

Tissue Doppler imaging: peak systolic (S*), peak early diastolic (E*), and peak atrial systolic (A*), isovolumetric relaxation time (IVRT*), isovolumetric

contraction time (IVCT*), duration of systole and diastole.

From these data, the following parameters are calculated: E*/A*, E/E*, systole*/ diastole*, and myocardial performance index (MPI).

2-D Speckle-tracking Echocardiography: left ventricle global longitudinal strain (LV GLS), radial strain and circumferential strain, peak twist rate, peak untwist rate.

Right ventricle:

Right ventricle dimensions: tricuspid valve annulus diameter, length, anterio-inferior dimension, mid cavity diameter, fractional area change (FAC-4ch), tricuspid annular plane systolic excursion (TAPSE).

Color-pooled Doppler (pulse wave): tricuspid valve peak early diastolic flow velocity (E), peak atrial flow velocity (A), pulmonary artery acceleration time (PAAT)

Tissue Doppler imaging: velocities (S*, E*, A*) and durations (ejection time, diastole, systole, isovolumetric relaxation time (IVRT*), isovolumetric contraction time (IVCT*).

2-D Speckle-tracking Echocardiography: peak longitudinal strain (pLS-4ch).

Secondary study parameters/endpoints (if applicable)

Secondary outcome

not applicable

Study description

Background summary

Neonates undergoing extracorporeal membrane oxygenation (ECMO) are subjected to an invasive therapy that provides temporary mechanical cardiopulmonary support for various reasons. In these neonates, cardiac function is threatened because of existing persistent pulmonary hypertension of the newborn (PPHN). This can cause a right to left shunt through fetal channels and leads to an increased afterload of the right ventricle, decreased preload of the left ventricle, and due to underlying pulmonary diseases to decreased oxygen delivery to the myocardium. During this therapy, clinicians use different techniques of hemodynamic monitoring. Nowadays, in this patient population echocardiography is used as a subjective tool for assessing global cardiac function. There is no objective assessment of heart function. There is a paucity of data outlining the role of conventional and novel echocardiographic derived parameters of cardiac function in patients that undergo ECMO, especially in the pediatric and neonatal population.

Study objective

To describe serial changes in diastolic and systolic myocardial performance by comprehensive echocardiographic assessment in neonates prior to, during, and after ECMO treatment and relate this to the course of PPHN.

Study design

Prospective observational cohort study.

Study burden and risks

The risks for the newborn infant are negligible, since the echocardiographic assessment is non-invasive and performed in a point-of-care setting.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

All neonates undergoing VA-ECMO and VV-ECMO in our ECMO center for the following diagnoses:
- Meconium aspiration syndrome
- Septicemia/pneumonia
- Congenital diaphragmatic hernia
- Idiopathic Pulmonary hypertension

Exclusion criteria

- Gestational age < 34 completed weeks
- Birth weight < 2000 grams
- Severe structural heart defect
- Pulmonary anomaly of which prognosis is known to be poor and considered irreversible
- Genetic or other major congenital or acquired abnormalities that are expected to be lethal on short notice
- Peri-/Intraventricular hemorrhage, * grade II
- Severe pre-existent coagulopathy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO Date:	18-06-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-01-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-10-2020
Application type:	Amendment
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

ID: 27732
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63370.091.17
Other	NTR aangemeld
OMON	NL-OMON27732