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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27732

Source
Nationaal Trial Register

Brief title
ECHMO

Health condition

Echocardiography, neonate, ECMO, heart function, tissue doppler, deformation imaging

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Radboudumc
Maquet

Intervention

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.

Secondary outcome

Conventional parameters of heart function

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.

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 population: Neonates undergoing VA-ECMO and VV-ECMO in a level III university hospital.

Exclusion: structural heart defects and cardiomyopathy.

Main study parameters/endpoints: 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.

Study objective

Prospective observational cohort study to obtain more insight in heart function of neonates undergoing ECMO

Study design

Prior to, during, and after ECMO.

During ECMO serial scans will be performed.

Intervention

Echocardiography during ECMO

Contacts

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Eligibility criteria

Inclusion criteria

Every neonate undergoing extracorporeal membrane oxygenation

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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2018
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-11-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46379
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6716
NTR-old	NTR6895
CCMO	NL63370.091.17
OMON	NL-OMON46379

Study results