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

Gepubliceerd: 28-11-2017 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27732

Bron
Nationaal Trial Register

Verkorte titel
ECHMO

Aandoening

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

Ondersteuning

Primaire sponsor: Radboudumc
Overige ondersteuning: Radboudumc
Maquet

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Prior to, during, and after ECMO.

During ECMO serial scans will be performed.

Onderzoeksproduct en/of interventie

Echocardiography during ECMO

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Every neonate undergoing extracorporeal membrane oxygenation

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2018
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-11-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46379
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten