Longitudinal microcirculatory changes in newborns with Congenital Diaphragmatic Hernia; an observational study

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To evaluate the predictive value of microcirculatory perfusion for the incidence of Extracorporeal Membrane Oxygenation (ECMO) dependency and consequently survival. To evaluate the effects of vasopressor drugs and iNO on microcirculatory perfusion...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON34367

Source
ToetsingOnline

Brief title
Microcirculatory changes in CDH

Condition

- Respiratory disorders congenital
- Neonatal and perinatal conditions

Synonym
Congenital Diaphragmatic Hernia

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: Diaphragmatic, Hernia, Microcirculation, Newborn

Outcome measures

Primary outcome

The main study endpoint is the incidence of ECMO dependency within the first day 28 of life and mortality within the first day 186 of life. Microcirculatory perfusion (depicted by PVD & MFI) will be assessed within 1 hour after admission for its predictive value.

Secondary outcome

To study microcirculatory perfusion in CDH patients on day 1 to 7 of life.

To study the effects of dobutamine, dopamine, epinephrine, norepinephrine (in relation to the vasopressor score) and iNO on microcirculatory perfusion in CDH patients.

To study the relation between microcirculatory perfusion (as measured by SDF) and routinely obtained macrocirculatory and microcirculatory parameters in CDH patients.

Study description

Background summary

Congenital diaphragmatic hernia (CDH) is a severe congenital (cardio)pulmonary disease associated with high morbidity and mortality. However, the spectrum of presentation and natural history are highly variable, varying from minimal or no symptoms, to acute, severe respiratory distress and hemodynamic instability with imminent death in the immediate newborn period. There is evidence to suspect microcirculatory alterations in CDH patients, which might prove to be independent from macrocirculatory alterations. Moreover, there is a diagnostic gap regarding tissue perfusion. Microcirculatory perfusion might prove to be

not only predictive for morbidity and/or mortality, but might be informative about the efficacy of vasopressor drugs and inhaled nitric oxide (iNO) as well. Limited studies have been performed using non-invasive functional biomarkers to study the microcirculation in critically ill children and CDH patients in particular.

Study objective

To evaluate the predictive value of microcirculatory perfusion for the incidence of Extracorporeal Membrane Oxygenation (ECMO) dependency and consequently survival. To evaluate the effects of vasopressor drugs and iNO on microcirculatory perfusion.

Study design

Investigator initiated, single center, observational, prospective case-control 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 daily for day 1-7 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

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 60, Postbus 2060
3000CB, Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 60, Postbus 2060
3000CB, Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Group 1: CDH patients
- Antenatal diagnosis of CDH
- Mother admitted to Obstetrics & Gynecology department, Erasmus MC-Sophia
- Parental informed consent ;Group 2: Control patients
Group 2A
- Control patients for group 1, matched for gender, PMA (±1 week) and age (± 1 day).
- Admittance to IC of Erasmus MC-Sophia
- Congenital malformations of the digestive tract
- Parental informed consent;Group 2B
- Control patients for group 1, matched for gender, PMA (±1 week) and age (± 1 day).
- Born in the Obstetrics & Gynecolgy department of Erasmus MC-Sophia
- Mother admitted to the Obstetrics & Gynecolgy department of Erasmus MC-Sophia
- Parental informed consent

Exclusion criteria

Group 1: CDH patients
- Non-antenatal diagnosis of CDH
- Outborn CDH patients
- Recurrent CDH
- Lung pathology mimicking diagnostic or clinical signs of CDH (diseases which should be excluded are diaphragmatic eventration, congenital cystic adenomatoid malformation (CCAML), bronchopulmonary sequestration, bronchogenic cysts, bronchial atresia, enteric cysts and teratomas)

- Severe chromosomal anomaly (i.e. trisomy 13 or trisomy 18), which imply abstinence of therapy
- Severe congenital cardiac anomaly (i.e. transposition of the great arteries, double outlet right ventricle, truncus arteriosus) with the exception of cardiac deformations associated with CDH (i.e. PDA, patent foramen ovale (PFO), small atrioventricular (AVSD) or atrioseptal defect (ASD))
- Cardiopulmonary resuscitation and subsequent therapeutic hypothermia;Group 2: Control patients
Group 2A & Group 2B
- Congenital anomalies or pathology of any kind known to influence cardiorespiratory functioning
- Use of vasopressor(s) (i.e. dobutamine, dopamine, epinephrine, norepinephrine) and/or iNO 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:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-08-2010
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	05-08-2010
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	NL32437.078.10