Evidence based therapy of pulmonary hypertension in congenital diaphragmatic hernia - A prospective observational study

Published: 19-10-2011
Last updated: 29-04-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON35811

Source
ToetsingOnline

Brief title
Evidence based therapy CDH

Condition

- Heart failures
- Gastrointestinal tract disorders congenital
- Neonatal respiratory disorders

Synonym
high pulmonary resistance, pulmonary hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Sophia stichting

Intervention

Keyword: biomarkers, congenital diaphragmatic hernia, echocardiography, pulmonary hypertension

Outcome measures

Primary outcome

The main study parameters are echocardiographic signs of pulmonary hypertension

in combination with plasma biomarkers (ICAM, VCAM, sP-selectin, VEGF, von

Willebrand factor, thrombomodulin, activated factor VIII:C, nitrate, nitrite,

ADMA, NT.pro BNP).

Secondary outcome

Microcirculatory perfusion (defined by the parameters PVD and MFI) at day 1-7

and at 2 hours after start of iNO, sildenafil and bosentan

Correlation with lactate, pH, MAP, pre- and postductal saturation, HF, Hb, Ht,

oxygen demand, need of ventilation

Drug and metabolite concentrations of sildenafil and bosentan

Population PK analysis

Pharmacodynamic analysis

Study description

Background summary

The development of pulmonary hypertension in infants born with a congenital diaphragmatic hernia has a major impact on the outcome concerning the mortality

and morbidity. Although the treatment has been improving over the last years, there are limited studies using macro- and mircocirculatory parameters in combination with plasmabiomarkers to follow the changes in pulmonary hypertension in these infants during therapy.

Study objective

The primary objective is to determine if echocardiography in combination with plasma biomarkers can be used as a potential predictor for pulmonary hypertension. The secondary objectives are assessment of a potential correlation between microcirculatory (SDF) and macrocirculatory (echocardiography) parameters and to study the effect of medical therapy with sildenafil and bosentan using pharmacokinetic and pharmacodynamic analysis.

Study design

Investigator initiated, single center, observational, prospective study.

Study burden and risks

Subjects will have no direct benefits of participating in this study. We aim to assess the objectives using echocardiography, Sidestream Dark Field Imaging (SDF), plasma biomarkers and as indicated drug and metabolite concentrations of sildenafil and bosentan. No adverse events have been reported using echocardiography and SDF. The expected burden for participants is very low, as the study procedure (echocardiography and SDF) is non-invasive and no radiation or other known damaging factors are involved. Total study procedure will take maximally 30 minutes (echocardiography) and 5 minutes (SDF) for each measurement. Standard, protocolized therapy will be monitored as this is an observational study. Other than echocardiography, SDF, plasma biomarkers and drug and metabolite concentrations patients will not be exposed to any additional medical or diagnostic procedures. No medical or diagnostic procedures will be postponed due to these measurements.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

All patients with congenital diaphragmatic hernia admitted to the ICU
Written parental informed consent

Exclusion criteria

Out born patients with congenital diaphragmatic hernia
Recurrent congenital diaphragmatic hernia
Lung pathology mimicking diagnostic or clinical signs of congenital diaphragmatic hernia
Severe chromosomal anomaly which imply abstinence of therapy
Severe congenital cardiac anomaly with the exception of cardiac deformations associated with congenital diaphragmatic hernia (patent ductus arteriosus, patent foramen ovale, atrioseptal defect)
Cardiopulmonary resuscitation and subsequent therapeutic hypothermia

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2011
Enrollment:	25
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-10-2011
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	NL36587.078.11