Physiological-based cord clamping for infants with congenital diaphragmatic hernia: a multicentre randomized controlled trial.

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Adopting a different approach at the time of delivery by using physiological-based cord clamping will protect the lung vasculature and thereby reduce the incidence and/or severity of pulmonary hypertension in the longer term.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26170

Bron
Nationaal Trial Register

Verkorte titel
PinC trial

Aandoening

Congenital diaphragmatic hernia, pulmonary hypertension, transition, cord clamping, resuscitation, birth defect.

Ondersteuning

Primaire sponsor: Erasmus MC, Rotterdam
Overige ondersteuning: Sophia Research Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pulmonary hypertension diagnosed in the first 24hrs after birth (binary variable).
Pulmonary hypertension is present if at least 2 of the following 4 criteria are present or if the infant requires extracorporeal membrane oxygenation (ECMO) in the first 24 hours after birth
- Right ventricular systolic pressure (RSVP) ≥ 2/3 systemic systolic pressure;
- Right ventricle (RV) dilatation/septal displacement, RV dysfunction +/- LV dysfunction;
- Pre-post ductal SpO2 difference >10%;
- Oxygenation Index >20.

Toelichting onderzoek

Achtergrond van het onderzoek

Congenital diaphragmatic hernia is the result of a developmental defect in the diaphragm, enabling abdominal organs to migrate to the thoracic cavity thereby interfering with pulmonary development. Most neonates born with a congenital diaphragmatic hernia (CDH) will develop respiratory insufficiency immediately after birth as a result of lung hypoplasia and will need invasive respiratory support. This is often combined with pulmonary hypertension (PH), a main determinant for survival. The etiology of PH is multifactorial and progressive vascular remodeling triggered by high perfusion pressures through the lung may be a potential factor. In this project we aim to investigate the implementation of physiological-based cord clamping (PBCC), i.e. achieving adequate lung aeration and perfusion before clamping of the cord, for infants with a CDH. We hypothesize that this approach is protective for the lung vasculature and thereby reduces the occurrence of PH. We will perform a multicenter randomized controlled trial and the primary outcome will be the occurrence of PH in the first 24 hours after birth.

Doel van het onderzoek

Adopting a different approach at the time of delivery by using physiological-based cord clamping will protect the lung vasculature and thereby reduce the incidence and/or severity of pulmonary hypertension in the longer term.

Onderzoeksopzet

Immediately after birth, it is restricted to either PBCC or standard of care. Further care will be according to standard protocol without difference between the two groups.

Onderzoeksproduct en/of interventie

CDH infants randomized to the intervention group will be stabilized according to physiological-based cord clamping (PBCC). For PBCC a specially designed resuscitation table (the Concord) will be used. Immediately after birth, the infant will be placed on the platform of the Concord, carefully avoiding any traction or pressure on the cord. The neonate will be intubated immediately after transfer to the table and respiratory support will be provided according to current clinical guidelines. The umbilical cord will not be clamped until the infant is stabilised. Stable is defined as the presence of a heart rate above 100 bpm and preductal oxygen saturation above 85% using a FiO2 of <0.5. The minimal and maximum time of cord clamping are three and ten minutes.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Infants antenatal diagnosed with isolated left-sided CDH with gestational age at delivery ≥35.0 weeks, in the absence of major structural or genetic abnormalities diagnosed before birth.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Right sided or bilateral CDH.

- Major associated anomalies (structural and/or genetic).
- Maternal contraindications of PBCC: anterior placenta praevia, placental abruption.
- High urgency caesarean section, with intended interval to delivery less than 15 min.
- Cases that have been treated during pregnancy with experimental drug therapy aiming to decrease the occurrence of pulmonary hypertension (such as sildenafil).
- Twin pregnancies in which the infant diagnosed with a CDH is born first
- Multiple birth > 2 (triplets or higher order).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	11-05-2020
Aantal proefpersonen:	140
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	03-07-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7853
Ander register	METC Erasmus MC : MEC-2019-0414

Resultaten

Samenvatting resultaten
N/A