Ventilaton, inflammation, perfusion and structure in Neontale Lung patients

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To develop a safe and fast MRI protocol for neonatal airway, lung and cardiac imaging in neonatal lung patients

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29625

Bron
NTR

Verkorte titel
VINyL

Aandoening

Bronchopulmonary dyslasia

Ondersteuning

Primaire sponsor: Erasmus MC- Sophia Children's Hospital
Overige ondersteuning: Vrienden van Sophia

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The technical qualitative assessment of the MRIs

Toelichting onderzoek

Achtergrond van het onderzoek

Bronchopulmonary dysplasia (BPD) is the most common respiratory disease in prematurely born children, with an incidence of up to 75% in neonates with a birthweight below 1000 grams. BPD is associated with increased risks of neonatal respiratory, cardiac and neurological symptoms and persists into childhood and adolescence. In our centre, BPD is currently monitored with lung function and Computed Tomography(CT). However, these monitoring methods have important downsides. For lung function, lung clearance index is only feasible in approximately 30% of the patients and reliable spirometry measurement is only possible from the age of 5 years onwards. CT is a sensitive technique to depict lung structure, but it is limited by exposure to radiation, which hampers its use for longitudinal follow up from early life onwards. Technical developments in Magnetic Resonance Imaging(MRI) of airways and lungs are quickly emerging, and have the potential to combine imaging of both lung structure and function. The feasibility in BPD patients is not yet fully clear.
The aim of this pilot study, the 'Ventilation, inflammation, perfusion and structure imaging in Neonatal Lung patients' (VINyL) study, is to develop a safe and fast MRI protocol for neonatal airway, lung and cardiac imaging in neonatal lung patients.
This prospective cross- sectional study will be performed at the Erasmus MC- Sophia, and is a collaboration between the departments of Pediatrics, divisions of Respiratory Medicine and Neonatology, and Radiology. All premature patients born before 28 weeks, who are admitted to the Neonatal Intensive Care Unit of the Erasmus MC- Sophia and are at risk for/have severe BPD, will be approached to participate. Patients will be compared to non- premature patients without pulmonary or cardiac comorbidities.
The main endpoint of this study is the technical qualitative assessment of the MRIs. Second, the ability of the MRI protocol to detect airway and lung ventilation, inflammation, perfusion and structural changes. Third, the MRIs of prematurely born infants will be compared to the MRIs of non- premature patients without pulmonary disease. Lastly, the technical feasibility of MRI to detect cardiac structures will be assessed. The VINyL findings will improve our understanding of the evolution and pulmonary and cardiac consequences of BPD in the neonatal phase. BPD- MRI will eventually help us to improve the clinical care and treatment options for this patient group. The development of a neonatal chest MRI protocol will be a milestone in the campaign of dose reduction in paediatric imaging.

Doel van het onderzoek

To develop a safe and fast MRI protocol for neonatal airway, lung and cardiac imaging in neonatal lung patients

Onderzoeksopzet

The study consist of one time point, the MRI

Onderzoeksproduct en/of interventie

MRI

Contactpersonen

Publiek

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0107036661

Wetenschappelijk

Erasmus MC- Sophia Children's Hospital
Bernadette Elders

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Premature: born before 28 weeks PMA, good enough clinical condition to undergo MRI, parents manage Dutch language, informed consent by parents, at 34-40 weeks PMA: still admitted at the Sophia Children’s Hospital, severe BPD according to NHI criteria or at risk for severe BPD (received 28 days of oxygen therapy)
Non- premature: born at a minimum of 37 weeks PMA, good enough clinical condition for MRI, parents manage Dutch language, informed consent by parents

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Premature:contraindication for MRI investigation, congenital cardiovascular or pulmonary abnormalities (other than caused by prematurity)
Non- premature:contraindication for MRI investigation, obtained mechanical ventilation, congenital cardiovascular or pulmonary abnormalities

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2019
Aantal proefpersonen:	18
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL7825
Ander register	METC Erasmus MC : MEC-2019-0378

Resultaten

Samenvatting resultaten
N/A