

Ventilation, inflammation, perfusion and structure in pediatric Bronchopulmonary dysplasia Erasmus

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MRI is a feasible, fast and safe technique for the long term follow up of neonatal and pediatric patient with bronchopulmonary dysplasia.

Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21082

Bron

Nationaal Trial Register

Verkorte titel

VIBE study

Aandoening

Bronchopulmonary dysplasia

Ondersteuning

Primaire sponsor: Erasmus MC- Sophia Children's Hospital

Overige ondersteuning: Vrienden van het Sophia

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcomes of this study are the pulmonary MR findings. All scans will be

evaluated on changes in ventilation, inflammation, perfusion and structure.
All data will be compared to the spirometry, LCI and MRI of two control groups: 1) premature non-BPD patients (born before <32 weeks without the diagnosis of BPD) 2) healthy volunteers.

Toelichting onderzoek

Achtergrond van het onderzoek

Background: 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 respiratory, cardiac and neurological symptoms and can evolve into chronic lung disease during childhood and adolescence. BPD is currently monitored with spirometry and Computed Tomography (CT). However, these monitoring methods have important downsides. Reliable spirometry measurement is not possible until the age of 5 years and spirometry outcomes have a poor sensitivity for changes in lung structure. CT is a sensitive technique to depict lung structure, but it has an important limitation due to exposure to radiation, which hampers its use for long term follow up and for evaluating combined structure-function information. Recent technical developments in pulmonary Magnetic Resonance Imaging (MRI) show promising results for safe and extensive combined imaging of structure and function in neonatal and pediatric BPD patients.

Objective of the study: The aim of this study is to develop a safe and fast MRI protocol for the imaging of neonatal and pediatric BPD patients. This METC application addresses the first part of the MRI- BPD project: 'Ventilation, Inflammation, perfusion and structure in pediatric Bronchopulmonary dysplasia Erasmus': VIBE study, the development of a pediatric BPD protocol. We will use MRI to image the lungs of pediatric BPD patients and evaluate these images on ventilation, inflammation, perfusion and structural changes.

Study design: This study is a prospective cross-sectional study performed at the Erasmus MC-Sophia Children's Hospital, The Netherlands and is a collaboration between the departments of pediatric pulmonology, neonatology and radiology.

Study population: All patients who have the diagnostic tag of BPD in the electronic patient file, are aged between 6 and 12 years old and who had/ will have a clinical routine pulmonary CT planned within six months of this study MRI, will be approached for this study. We aim to enrol 10 BPD patients. Data will be compared to normative data obtained from 10 age matched healthy volunteers.

Intervention: After informed consent, all patients and volunteers will undergo spirometry, multiple breath washout (MBW) measurement and the MRI protocol.

Research goal: This VIBE study is the first phase of the development of a neonatal and pediatric BPD-MRI protocol, for the clinical follow up of all BPD patients. The VIBE findings will improve our understanding of the long term pulmonary consequences in BPD patients. BPD-MRI will eventually help us to improve the clinical care and treatment options for this patient group.

Doel van het onderzoek

MRI is a feasible, fast and safe technique for the long term follow up of neonatal and pediatric patient with bronchopulmonary dysplasia.

Onderzoeksopzet

All tests will be conducted at one timepoint.

Onderzoeksproduct en/of interventie

Spirometry, multiple breath washout and MRI

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Diagnosis of BPD according to the NHI criteria, aged between 6-10 years, will have/has a CT scan planned within 6 months of this research, informed consent by parents (and patient).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Inability to undergo MRI, inability to follow instructions in the MRI, current severe lung infection (symptoms of respiratory distress, severe coughing, antibiotic use), chronic oxygen use

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Anders
(Verwachte) startdatum:	01-09-2018
Aantal proefpersonen:	10
Type:	Onbekend

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	NL7087
NTR-old	NTR7285
Ander register	METC Erasmus MC : MEC-2018-134

Resultaten