Ventilation Inflammation Perfusion and Structure in pediatric Bronchopulmonary Dysplasia Erasmus

Published: 30-07-2018
Last updated: 11-04-2024

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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal respiratory disorders
Study type	Observational invasive

Summary

ID

NL-OMON49241

Source
ToetsingOnline

Brief title
VIBE study

Condition

- Neonatal respiratory disorders

Synonym
Bronchopulmonary dysplasia, underdeveloped lungs

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Bronchopulmonary dysplasie, magnetic resonance imaging, pediatric

Outcome measures

Primary outcome

The main endpoint of this study is the ability of the MRI protocol to detect structural lung changes related to BPD as established using the VIBE- scoring system, evaluating normal lung tissue, low intensity regions, ventilation defects, presence of airway wall thickening, consolidations and severity of architectural distortion.

Secondary outcome

A technical qualitative assessment of the MRIs will be done. The MRI findings will be correlated to spirometry data, MBW measurements and compared to the CT findings.

Study description

Background summary

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.

Study objective

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

Study burden and risks

Participation in this study consists of a three-hours visit to the Sophia Children*s Hospital. This visit will consist of a physical examination (10 minutes), spirometry and instructions for the spirometry-controlled MRI (30 minutes), MBW measurement (20 minutes), training in a dummy MRI (15 minutes) and the MRI protocol (30-45 minutes). If applicable and possible in the radiology planning and if requested by parents/patient the clinically ordered pulmonary CT scan can be planned on the same day. None of these procedures are associated with a direct risk for the patient. Nitrogen MBW is a safe technique, without risk for the children. MRI is a radiation free technique without risk for the children. The only adverse effect is related to the noisy and restricted environment of the MRI scanner that can induce claustrophobia. Appropriate training will be performed to minimize the risk for claustrophobia, and each subject will have the opportunity to withdraw from the study at any moment of the study. A benefit for the patients will be that the data obtained from the MRI, spirometry and MBW measurement will be available for the treating physician to be used for clinical treatment. 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.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015CN
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015CN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Patients: diagnosis of BPD according to NHI criteria, age between 6 and 16 years, (in half of the BPD patients,n<=6) routine clinical CT scan planned in the next six months or received a clinically ordered spirometry controlled CT in the past six months, informed consent by parents/patient, Premature- non BPD volunteers: age between 6 and 16 years, born <32 weeks of gestation, informed consent by parents/patient, Healthy volunteers: age between 6 and 16 years, informed consent by parents/patient

Exclusion criteria

Patients: contra- indications for MRI, inability to follow instructions in the MRI, current severe lung infection (respiratory distress, severe coughing, antibiotic use for lung infection), chronic oxygen need, Premature non- BPD patients: contra- indications for MRI, inability to follow instructions in the MRI, current severe lung infection (respiratory distress, severe coughing, antibiotic use for lung infection), chronic oxygen need, diagnosis of BPD, Healthy volunteers: contra- indications for MRI, inability to follow instructions in the MRI, current severe lung infection (respiratory distress, severe coughing, antibiotic use for lung infection), chronic oxygen need, born at a gestational age of less than 37 weeks, presence of pulmonary comorbidities (asthma, cystic fibrosis, interstitial lung disease etc.)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-05-2019
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	30-07-2018

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-12-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-03-2020
Application type:	Amendment
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	NL66451.078.18