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

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21082

Source
Nationaal Trial Register

Brief title
VIBE study

Health condition

Bronchopulmonary dysplasia

Sponsors and support

Primary sponsor: Erasmus MC- Sophia Children's Hospital
Source(s) of monetary or material Support: Vrienden van het Sophia

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

A qualitative and feasibility check of all MRIs will be done. Furthermore, all the MRI findings will be compared to the spirometry and multiple breath washout measurements and a clinically ordered pulmonary CT made within six months of the research MRI.

Study description

Background summary

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 electronical 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.

Study objective

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

Study design

All tests will be conducted at one timepoint.

Intervention

Spirometry, multiple breath washout and MRI

Contacts

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Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-09-2018
Enrollment:	10
Type:	Unknown

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL7087
NTR-old	NTR7285
Other	METC Erasmus MC : MEC-2018-134

Study results