Ventilaton, inflammation, perfusion and structure in Neontale Lung patients

No registrations found.

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

Summary

ID

NL-OMON29625

Source
NTR

Brief title
VINyL

Health condition

Bronchopulmonary dyslasia

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

The technical qualitative assessment of the MRIs

Secondary outcome

The ability of the MRI protocol to detect airway and lung ventilation, inflammation, perfusion

and structural changes. Furthermore, the MRIs of prematurely born infants will be compared to the MRIs of non- premature patients without pulmonary disease. And lastly, the technical feasibility of MRI to detect cardiac structures will be assessed.

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 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.

Study objective

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

Study design

The study consist of one time point, the MRI

Intervention

MRI

Contacts

Public
Erasmus MC- Sophia Children's Hospital
Bernadette Elders

0107036661
Scientific
Erasmus MC- Sophia Children's Hospital
Bernadette Elders

0107036661

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2019
Enrollment:	18
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

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	NL7825
Other	METC Erasmus MC : MEC-2019-0378

Study results

Summary results
N/A