Ventilation Inflammation Perfusion and Structure in Neonatal Lung patients

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

Summary

ID

NL-OMON54975

Source
ToetsingOnline

Brief title
VINyL 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 technical qualitative assessment of the MRIs.

Secondary outcome

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 and the MRI findings will be compared to the EIT measurement.

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.

Study objective

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.

Study design

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. After informed consent all premature patients and non- premature patients will undergo thoracic MRI and echocardiography and EIT measurement.

Study burden and risks

Participation in this study consist of an MRI at the Erasmus MC-Sophia, the MRI protocol takes 45-60 minutes, furthermore an echocardiography will be included for non-premature patients, taking 30 minutes, this is already clinical protocol in premature patients. Lastly, an EIT measurment will take place which takes 10 minutes.The study participants will not receive sedation, instead they will be fed and swaddled, therefore half an hour preparation before the scan will be necessary. MRI is a radiation free imaging method with minimal risk for the patient. Moreover, we aim to use a noiseless high-resolution scan during free-breathing, known as zero-TE (ZTE) or *silent MRI*. The only possible adverse events are minimal chances of overstimulation or tiredness with sometimes hemodynamic, respiratory or temperature instability. These events will be overcome by providing a safe environment with feeding and swaddling (if possible by the caregivers), appropriate noise protection, an MRI compatible incubator with hemodynamic and respiratory control with the use of MRI compatible equipment and guidance by neonatal resuscitation trained physicians/ nurses. A potential benefit for the patients will be that the radiological results will be available for the treating physicians and might be used in clinical care. 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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Newborns

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

Exclusion criteria

Premature: contraindication for MRI investigation
Non- premature: contraindicatie for MRI investigation, congenital

cardiovascular or pulmonary abnormalities, obtained mechanical ventilation

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:	Completed
Start date (anticipated):	05-06-2020
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO Date:	14-08-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-06-2022
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	NL70484.078.19
Other	NL7825

Study results

Date completed: 01-02-2024

Summary results
Trial ended prematurely