Advanced Imaging in Chronic Pediatric Pulmonary Disease (CPPD)

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Primary Aim: to validate 3D Spiro MRI against PCD-CT for accurate phenotyping and sensitive monitoring of children with CPPD, by assessing disease severity in term of regional lung structural and functional changes compared to PCD-CT.Secondary aim(s...

Ethical review	Approved WMO
Status	Pending
Health condition type	Congenital respiratory tract disorders
Study type	Observational non invasive

Summary

ID

NL-OMON57065

Source
ToetsingOnline

Brief title
ADVANCER study

Condition

- Congenital respiratory tract disorders

Synonym
Cystic Fibrosis; Asthma; BPD

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Horizon 2023

Intervention

Keyword: Asthma, BPD, Cystic Fibrosis, MRI

Outcome measures

Primary outcome

The primary study endpoint is to investigate whether 3D Spiro MRI can be used to assess CCPD compared to PCD-CT:

N=90 Research MRIs - PRIME score

N=90 Clinical PCD-CTs - PRAGMA score

PRAGMA score quantifies lung abnormalities in a hierarchical order, with results expressed as % of total lung volume.

PRIME score is an adapted version of the PRAGMA score, for the MRI scan.

Secondary outcome

To address the secondary aims, the following secondary study parameters will be collected:

• PFTs outcomes

o Spirometry (FEV1, FVC, FEV1/FVC, FEF25-75 and FEF75)

o Multiple breath washout (Lung clearance index)

o Oscillometry at 5-11-19Hz

• Research questionnaires data

• N=90 Research MRIs - 3D Spiro MRI biomarkers (17), PREFUL MRI outcomes (21)

• N=90 Clinical PCD-CTs - BronchusArtery (BA) ratios, Ventilation estimation from registered analysis (VERA) analysis scores, Pulmonary Artery and Vein

analysis outcomes

Study description

Background summary

Chronic pediatric pulmonary diseases (CPPD) include a large range of pulmonary diseases, such as cystic fibrosis (CF), bronchopulmonary dysplasia (BPD) and asthma. These diseases have a significant impact on patient*s quality of life and survival. Recent development of the Photon counting detector CT (PCD-CT) opens up new possibilities to significantly reduce radiation dose without reduction of image quality. Secondly, a recently developed magnetic resonance imaging (MRI) techniques provide new insight in pulmonary diseases. 3D MRI spirometry is a new MRI technique that combine structural and functional information in a single examination as radiation-free alternative to chest CT. There is a need of new safe and precise objective measure to monitor CPPD.

Study objective

Primary Aim: to validate 3D Spiro MRI against PCD-CT for accurate phenotyping and sensitive monitoring of children with CPPD, by assessing disease severity in term of regional lung structural and functional changes compared to PCD-CT. Secondary aim(s): to assess a) the regional lung mechanics with respect to disease severity and establish reference flow-volume loop maps using 3D Spiro MRI; b) chest-CT protocol improvement for monitoring CF and BPD patients in term of resolution, dose, and disease quantification using the new PCD-CT technology compared to historical CF, BPD and asthma cohorts; c) to define sensitivity of 3D Spiro MRI compared to PCD-CT, Pulmonary Function Tests (PFTs) and Quality of life (QoL) questionnaires to quantify structural and functional changes in the CF, BPD and asthma cohorts; d) the relation between ventilation MRI parameters derived from 3D Spiro MRI with ventilation parameters obtained from PREFUL MRI and low intensity region (LIR) and low attenuation region (LAR) quantified from expiratory MRI and CT and PFT (LCI) and e) how children with CPPD and their caregivers experience the two procedures, and whether and how it affects their understanding, imagination and feelings of their body and disease.

Study design

Prospective and retrospective study

Study burden and risks

This study includes one visit to the hospital for the patients. The patients

are routinely referred for a CT scan in order to monitor disease progression as part of current follow-up scheme for CF and BPD patients. For asthma patients, CT is usually indicated when not responding to treatment to exclude other cause of pulmonary symptoms. The additional MRI scan will require a longer stay at the hospital for examination, but will not contribute to any additional radiation exposure. MRI protocol will not include the use of any contrast. Due to the choice to include children above the age 5, no anaesthesia will be required.
MRI scanners are rather loud operating machines; therefore a child might feel scared to undergo the scanning procedure. However, standard operating procedure and demonstration video are already in use to make the entire MRI experience less cumbersome. The study interventions also will include health status questionnaires and interview with researcher(s) to describe experience with both MRI and CT technique.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)

Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

CF Cohort
• children aged 5 to 18 years
• CF patients referred for an annual follow-up

BPD Cohort
• children aged 5 to 18 years
• BPD patients referred for follow-up

Asthma Cohort
• children aged 5 to 18 years
• Difficult-to-treat asthma children referred for CT examination

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• Children diagnosed with CF, difficult to treat asthma or BPD under the age of 5
• Pulmonary exacerbation (CF and Asthma)
• Claustrophobia
• Inability to perform the breathing manoeuvres
• Any contraindication(s) to undergo MRI

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2024
Enrollment:	90
Type:	Anticipated

Ethics review

Approved WMO

Date:	31-10-2024
Application type:	First submission
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	NL85470.078.23