central airways and lung volume assessment by Magnetic Resonance Imaging in children

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Primary objective: to evaluate the image quality between the two protocols using Signal to Noise Ratio (SNR) measurements Secondary objectives: 1) test if measurements of lung volume and central airways dimensions using MRI are related to validated…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON41163

Source
ToetsingOnline

Brief title
lung MR protocol in children

Condition

- Respiratory disorders congenital
- Congenital respiratory tract disorders

Synonym
astma cystic fibrosis

Research involving
Human

Sponsors and support

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

Onderzoek

Intervention

Keyword: astma, children, cystic fibrosis, lungs

Outcome measures

Primary outcome

The main endpoint of this study is to test an improved lung MRI protocol for children. Our proposed protocol was first optimized in a group of adult volunteers. We will assess the reliability of repeated measurements of lung volume and central airways* dimensions using MRI in three groups of children aged 8 -18 years old.

The main parameters assessed will be:

• Intra and inter-observer variability for multiple measurements of lung volumes and central airways dimensions (i.e. cross-sectional areas) on MRI
• Absolute and relative differences in lung volumes and central airways* dimensions computed by MRI, helium dilution, plethysmography and in the CF group only, from the last CT scan performed in the 12 months prior to the MRI.
• Correlations between lung function measurements related to volume (TLCbb, TLChe, FVC; TLCbb-RV) and MRI and, in the CF patients only, volumes from the previous CT as these values already exist and as an additional assessment of the robustness of the lung volumes calculated from these new sequences.

• Correlations between spirometry measurements related to central airway dimensions (FEV1; PEF) and MRI central airway dimensions

• Correlations between lung function measurements related to small airways disease (TLCbb-TLChe; RV, RV/TLC; FEF25-75, FEF75) and volume of trapped air on MRI assessed by both the standard CF lung volume MRI protocol and the new proposed MRI protocol

Secondary outcome

The secondary objectives of this study are:

• test if measurements of lung volume and central airways dimensions using MRI are related to validated pulmonary function tests in children with respiratory disorders and healthy controls;

• to assess the ability of a new MRI sequence protocol to detect TA.

Study description

Background summary

MRI offers a safe, radiation free imaging technique to evaluate structural lung damage and improve our understanding of the pathophysiology of paediatric asthma and cystic fibrosis (CF). Identification of early structural airway and lung volume changes in both CF and asthma is needed to adjust treatment aimed at preventing irreversible structural lung changes. Advances in MRI sequencing protocols have improved the capacity of MRI to detect changes in lung structure. We speculate that in CF and asthma, central airway dimensions may be reduced due to airway wall thickening (AWT) and that the reduced lung volume commonly reported in CF and may also be present in asthma patients. We hypothesise that the new MRI protocol will be superior to the previous protocol at calculating lung volumes and central airways dimensions, and subsequently improve the detection and quantification of TA in both CF and asthma disease pathologies.

Study objective

Primary objective: to evaluate the image quality between the two protocols using Signal to Noise Ratio (SNR) measurements Secondary objectives:
1) test if measurements of lung volume and central airways dimensions using MRI are related to validated pulmonary function tests in children with respiratory disorders and healthy controls;
2) assess capacity to detect TA in a new MRI protocol

Study design

Single centre, cross-sectional hospital-based study

Study burden and risks

The burden associated with participation in this study is minimal. for CF patients the MRI protocol is only 15 minutes longer than the routinely used lung MRI protocol because additional improved sequences have been added. CF patients are familiar with this MRI procedure as they routinely have a lung MRI every second year as part of their annual examination. For CF patients, the extra MRI will be scheduled in combination with a routine visit or with the annual examination wherever possible. For asthmatic and healthy controls, participation will involve an extra visit to the Sophia Children*s Hospital on one occasion specifically for the study. Asthmatic children are used to lung function measurements and some of them will have had an MRI.For the healthy chidren everything will be new, maybe their sick brother /sister can support them if needed.
An experienced lung function technician will guide the children during the whole visit.
The primary benefits of participation in this study are that the new protocol may improve detection and quantification of structural changes in the CF and asthma patients which otherwise would not have been detected. There is no direct benefit to healthy children participating in this study. Healthy children are required as a control reference population to quantify lung volume and airway dimensions using the new MRI sequences.

The only perceivable risk to the children in this study is that performing an MRI may induce claustrophobia. This risk is negligible as all available methods to familiarise the children and reduce this risk will have been implemented prior to performing the MRI. If claustrophobia occurs, the child will be withdrawn from the MRI machine immediately, and withdrawn from the study.

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

•Age between 8 - 18 years;
• Clinical diagnosis of CF confirmed by a positive sweat test or two CF-related mutations OR
• Clinical diagnosis of asthma as confirmed by treating physician OR;
• Healthy child as determined by no history of respiratory disease or congenital deformities.
• Ability to perform lung function tests.
• Written informed consent from parents/caregivers

Exclusion criteria

•Inability to follow instructions of the investigator
•Claustrophobia
•Any clinical condition which, according to the treating physician, might put the patient at risk
•For CF patients: respiratory tract infection requiring IV antibiotics in the last 4 weeks
•For asthma patients: exacerbation requiring a course of oral corticosteroids in the last 4 weeks

any question answered with YES on the MRI questionnaire on contra indications

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:	Recruiting
Start date (anticipated):	25-02-2015
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO Date:	30-07-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-06-2015
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	NL47950.078.14
Other	nummer aangevraagd