Lung MR in children

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22658

Bron
Nationaal Trial Register

Verkorte titel
Lung MR in children

Aandoening

cystic fibrosis, astma

Ondersteuning

Primaire sponsor: erasmus Mc
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• Signal to Noise Ratio (SNR) between the current clinical protocol (MRI1) and the proposed protocol (MRI2)
• Intra and inter-observer variability for multiple measurements of lung volumes, central airways' dimensions (i.e. cross-sectional areas) on MRI

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Objective of the study
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 ratio (SNR) 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 population
Children aged 8 – 18 years treated for CF or asthma and healthy siblings of these children.

Primary study parameters
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.

Secondary study parameters
The secondary objectives of this study are: 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)to assess the ability of a new MRI sequence protocol to detect TA.

The burden associated with participation in this study is minimal. 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.

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.

Doel van het onderzoek

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.

Onderzoeksopzet

One visit of max 2 hours

Onderzoeksproduct en/of interventie

MRI and lung function tests

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Aged 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 parent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2014
Aantal proefpersonen:	36
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4298
NTR-old	NTR4442
Ander register	METC Erasmus MC : 2014-073

Resultaten