Central airways mechanics

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The new MRI protocol will be sensitive enough to detect a diagnostic change of > or = 50% change from the normal normal shaped trachea.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28602

Bron
NTR

Verkorte titel
CAM

Aandoening

tracheobronchomalacia (TBM)
tracheabronchomalacie
Central airway mechanics

Ondersteuning

Primaire sponsor: ErasmusMC/ Sophia

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

sensitivity and specificity of MRI as a diagnostic tool to assess central airway collapsibility

Toelichting onderzoek

Achtergrond van het onderzoek

: Central airways mechanics in pediatric diseases is little known in vivo. Acute and chronic airway inflammation can produce increase softness of the tracheal and bronchial wall, with so resulting tracheobronchomalacia (TBM) (1).Central airways are mostly assessed with flexible bronchoscopy and CT. Bronchoscopy is considered the gold standard modality, because it allows direct visualization of the airway. However, bronchoscopy is an invasive technique, limited to assessment during tidal breathing and requiring general anaesthesia (3). For these reasons, CT is combined with bronchoscopy. CT has high temporal and spatial resolutions that allow direct and precise measurement of the central airway. Moreover CT supplies additional information about the structures surrounding the airway and about the lung parenchyma. One limitation of CT is the radiation exposure that for pediatric patient is still matter of concern.To overcome this limitation of CT, magnetic resonance imaging (MRI) has been introduced in airway imaging. MRI is a free-radiation technique that enables repeated and dynamic acquisition (8). Dynamic acquisitions (cine-MRI) are needed for better understanding central airways mechanics, because they elicit the driving forces that regulate inspiratory and expiratory changes. The diagnostic performance of cine-MRI has never been compared to bronchoscopy. If MRI will prove to be as good as bronchoscopy to diagnose central airways diseases, it will be possible to reduce the number of invasive bronchoscopy. We developed a new MRI protocol for airway imaging that proved to be feasible in pediatric patients (9).

Objective: We hypothesize that the new MRI protocol will be sensitive enough to detect a diagnostic change of ¡Ý 50% change from the normal shaped trachea. To test this hypothesis, the primary objective of this study is to determine sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of our MRI protocol compared to flexible bronchoscopy, used as reference test. Secondary aims include: 1) assessing concordance between TBM severity, as determined by MRI and bronchoscopy; 2) relationship between severity assessment of MRI and bronchoscopy with pulmonary function tests (PFT) and respiratory symptoms; and 3) to assess the influence of bronchodilator in airways mechanics.

Study design: Prospective, observational study

Study population: children aged 6 years and above referred to Sophia Children¡¯s Hospital for bronchoscopy. A total of 60 patients who are already scheduled for a bronchoscopy under general anaesthesia will be recruited.

Intervention (if applicable): Not applicable

Main study parameters/endpoints: The diagnostic performance of MRI to assess central airways cross-sectional changes in comparison to bronchoscopy, the current gold standard to diagnose airway diseases.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participation in the study will add an extra visit to Sophia Children¡¯s Hospital. Total visit time will be approx. 1.45 hours: 40 minutes MRI scanning, 55 minutes lung function testing, training and bronchodilator (including 10 minute break), and 10 minutes for consent and questionnaire. Early and safe diagnosis of airway disease is beneficial in initiating appropriate treatment such as earlier commencement of antibiotic treatment during winter months. Finally, appropriateness of using bronchodilators for TBM symptoms, the most common, but potentially least appropriate treatment of TBM symptoms, will be assessed.

Doel van het onderzoek

The new MRI protocol will be sensitive enough to detect a diagnostic change of > or = 50% change from the normal normal shaped trachea.

Onderzoeksopzet

60 patients in two years

Onderzoeksproduct en/of interventie

MRI

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Indication for bronchoscopy as decided by the treating paediatric chest physician;

• Aged 6 years or above;

• Ability to perform spirometry and spirometry controlled or technician controlled MRI

• Informed consent from the parents / guardians.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Any contraindications to MRI

• In the case any contra indications to administering bronchodilator, this part of the protocol will be omitted

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2016
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-03-2016
Soort:	Eerste indiening

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	NL5787
NTR-old	NTR5950
Ander register	: MEC2016-235

Resultaten