# Assessment of central airways mechanics using Magnetic Resonance Imaging (MRI) and bronchoscopy: a comparison

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital respiratory tract disorders
Study type	Observational invasive

## Summary

#### ID

NL-OMON43232

**Source** ToetsingOnline

Brief title Central Airways Mechanics (CAM)

### Condition

• Congenital respiratory tract disorders

**Synonym** tracheo malacia

**Research involving** Human

### **Sponsors and support**

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam **Source(s) of monetary or material Support:** Ministerie van OC&W

#### Intervention

Keyword: bronchoscopy, central airway mechanics, MRI

#### **Outcome measures**

#### **Primary outcome**

The main study parameter is the sensitivity and specificity of MRI as a diagnostic tool for static and dynamic assessment of airway collapsibility in children. We will determine sensitivity, specificity, PPV and NPV of our MRI protocol compared to flexible bronchoscopy to assess airway collapsibility, the current gold standard for airway assessment in pediatric patients.

#### Secondary outcome

Secondary study parameter is the severity scores of airway collapsibility using MRI and bronchoscopy. Concordance between MRI and bronchoscopy airway collapsibility severity scores will be assessed. Airway collapsibility for both MRI and bronchoscopy will be scored both with categorical and continuous variables.

## **Study description**

#### **Background summary**

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). For instance, in a study with Cystic Fibrosis (CF) patients, TBM was diagnosed in 69% of the subjects. Differently, when airway inflammation heals by fibrosis, this can result in airway stenosis. This type of healing process is common in diseases such as relapsing polychondrithis, endobronchial tuberculosis or prolonged intubation.

Central airways are mostly assessed with flexible bronchoscopy and CT.

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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. Assessments of airway shapes and cross-sectional area (CSA) during bronchoscopy are troublesome since they are influenced by anesthetic agents, intrathoracic and airway pressures, gas-flow dynamics, and lung volume. Additionally, objective airway dimension measurement is compromised during bronchoscopy due to optical distortions caused by the fish eye shaped lens. 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. 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.

#### **Study objective**

We hypothesize that the new MRI protocol will be sensitive enough to detect a diagnostic change of >= 50% change from the normal shaped trachea. The primary objective of this study is to determine sensitivity, and specificity, of our MRI protocol compared to flexible bronchoscopy, used as reference test

#### Study design

Prospective, observational study

#### Study burden and risks

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.

## 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**

Indication for bronchoscopy as decided by the treating pediatric chest physician Aged 8 years or above Ability to perform spirometry and spirometry controlled or technician controlled MRI Informed consent from the parents/ guardians

### **Exclusion criteria**

Any contra indication for MRI In the case any contra indications to administer bronchodilator, this part of the protocol will be omitted

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## Study design

### Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	16-10-2017
Enrollment:	60
Туре:	Actual

## **Ethics review**

Approved WMO	
Date:	05-07-2016
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

ССМО

**ID** NL57040.078.16