

# Central airways mechanics

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON28602

### Source

NTR

### Brief title

CAM

### Health condition

tracheobronchomalacia (TBM)  
tracheabronchomalacie  
Central airway mechanics

## Sponsors and support

**Primary sponsor:** ErasmusMC/ Sophia

## Intervention

## Outcome measures

### Primary outcome

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

### Secondary outcome

to assess concordance between MRI and bronchoscopy  
airway lumen reduction scores of both MRI and bronchoscopy to assess associations between

## 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) (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  $\geq 50\%$  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.

### **Study objective**

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

### **Study design**

60 patients in two years

### **Intervention**

MRI

## **Contacts**

### **Public**

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### **Scientific**

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## Eligibility criteria

### Inclusion criteria

- 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.

### Exclusion criteria

- Any contraindications to MRI
- In the case any contra indications to administering bronchodilator, this part of the protocol will be omitted

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2016
Enrollment:	60
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	03-03-2016
Application type:	First submission

## 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
NTR-new	NL5787
NTR-old	NTR5950
Other	: MEC2016-235

## Study results