Magnetic resonance imaging of the upper airways in children

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Observational invasive

Summary

ID

NL-OMON46525

Source
ToetsingOnline

Brief title
MUSIC study

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
airway stenosis, laryngeal stenosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: laryngeal stenosis, larynx, MRI, pediatric

Outcome measures

Primary outcome

The primary outcomes of this study are the findings on MRI. In the first sub study we will classify post-surgical changes, this will compared to the normal anatomy of the larynx in healthy children. In the second sub study we will quantify the extent and location of fibrosis. Lastly, in the third sub study, we will quantify the mobility of the vocal cords. This will compared to the normal vocal cord mobility as seen in healthy children.

Secondary outcome

The MRI findings from the first and second sub study will be correlated to clinical status. Clinical status will be assessed through health related questionnaires and spirometry. Findings from the third sub study will be correlated to the rate of dysphonia assessed by the Dysphonia Severity Index and voice questionnaires.

Study description

Background summary

Pediatric laryngeal stenosis (LTS) has various congenital and acquired causes. Open airway surgery, through laryngotracheal reconstruction or cricotracheal resection, is done to repair the airway without tracheostomy, while maintaining swallowing and vocal function. Although the rate of successful surgical interventions has improved over the last decades, sequelae, such as respiratory complaints and dysphonia, are not uncommon. Anatomical and functional risk factors leading to these sequelae are not well understood. Imaging of the larynx post- surgery is likely to improve our understanding of these

pathophysiological risk factors. The development of Magnetic Resonance Imaging (MRI), as an ionizing radiation- free alternative to Computer Tomography, provides opportunities for safe morphological and functional imaging of the upper airway in these children.

Study objective

The overall aim of the study is to correlate the anatomical and functional anatomy of the larynx, as seen on MRI to various functional outcome measures in patients who underwent open airway surgery for LTS. The specific aims of this study are: 1) to correlate anatomical changes related to surgery, as seen on MRI, to clinical outcome, 2) to correlate the extent and location of fibrosis, as seen on MRI, to clinical outcome and 3) to correlate dynamical vocal cord function, as seen on MRI, to dysphonia. We hypothesize that MRI can be used as an imaging technique, without the need for sedation and without the exposition to ionizing- radiation, for extensive morphological and dynamic evaluation of the pediatric larynx.

Study design

This study is a prospective cross- sectional study performed at the Erasmus MC-Sophia Children*s Hospital in Rotterdam, the Netherlands.

Study burden and risks

Participation in this study will consist of a four hour visit to the Sophia Children*s Hospital. The visit will consist of filling in questionnaires and recording medical history (30 minutes), physical examination (10 minutes), spirometry (30 minutes), vocal test (20 minutes), visit mock MRI (25 minutes) and MRI (30- 45 minutes). None of these procedures are associated with a direct risk for the patient. MRI is a radiation free technique without risk for the children. The only adverse effect is related to the noisy and restricted environment of the MRI scanner that can induce claustrophobia. Appropriate training will be performed to avoid this adverse effect, and each subject will have the opportunity to withdraw from the study at any moment. The main benefit for this group of children will be a better understanding of anatomical and functional risk factors related to adverse outcome post-open airway surgery. A better understanding of these factors will improve the healthcare for this patient group, the better quantification of post- surgical anatomical changes will help develop future interventions and will allow for the development of tailored management programs according to the specific morphological and/or functional deficit. In addition, the further developed MRI of the pediatric larynx, could replace potentially harmful current imaging methods.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015CN
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015CN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Patient: undergone surgical reconstruction for a congenital or acquired laryngeal stenosis between 1994 and 2018(6-30 years), able to follow instructions during MRI, informed consent by parents and/or patient
Volunteer: age between 6 and 30 years, able to follow instructions during MRI, informed consent by parents and/or volunteer

Exclusion criteria

Patient: contra- indications for MRI, inability to undergo MRI, any current lung infection (symptoms of respiratory distress, severe cough, antibiotics for current lung infection), chronic oxygen need, tracheotomy cannula in situ
Volunteer: contra- indications for MRI, inability to undergo MRI, any current lung infection (symptoms of respiratory distress, severe cough, antibiotics for current lung infection), chronic oxygen need, co- morbidities of the lungs, airways or vocal cords

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:	Recruitment stopped
Start date (anticipated):	22-05-2018
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	20-04-2018
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	ID
CCMO	NL64497.078.17