Magnetic Resonance Imaging of the upper airway in children

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26869

Source
Nationaal Trial Register

Brief title
MUSIC study

Health condition

Laryngeal stenosis

Sponsors and support

Primary sponsor: Erasmus MC- Sophia Children's Hospital
Source(s) of monetary or material Support: Vrienden van Sophia

Intervention

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. 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.

Secondary outcome

The MRI findings from the first and second sub study will be correlated to clinical status. Clinical status will be assessed through patient history, health related questionnaires, physical examination 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

Background:

Pediatric laryngeal stenosis (LTS) has various congenital and acquired causes. Open airway surgery 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.

Objective of the study:

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 population:

Patients will be recruited from the Ear Nose Throat outpatient clinic who underwent open airway surgery for LTS between 1994 and 2011. We aim to enrol at least 50 patients. Data will be compared to 10 healthy controls.

Outcomes:

The primary outcomes of this study are the findings on MRI. In the first sub study we will classify post-surgical changes. 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. The MRI findings from the first and second sub study will be correlated to clinical status, 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.

Aim:

Our aim for this group of children is to better understand 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.

Study objective

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

All tests (questionnaires, spirometry, vocal test, MRI) will be conducted at one timepoint.

Intervention

Health- and voice related questionnaires, MRI, spirometry, vocal test

Contacts

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Eligibility criteria

Inclusion criteria

Undergone surgical reconstruction for a congenital or acquired laryngeal stenosis between 1994 and 2011 (minimum 6 years of age), informed consent by parents and/or patient

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-04-2018
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-12-2017
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	NL6746
NTR-old	NTR6924
Other	: MEC-2018-013

Study results