Follow-up of infants and children surgically treated for an acquired laryngeal stenosis after endotracheal intubation

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Primary Objectives: 1. To determine the consequences in infants and children who had a laryngotracheal reconstruction or cricotracheal resection, regardinga. quality of the voiceb. physical strain Secondary objectives:2. To determine the…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON34296

Source
ToetsingOnline

Brief title
Follow-up of children surgically treated for acquired laryngeal stenosis

Condition

- Other condition

Synonym
larynxstenosis, narrowing of the upper airway

Health condition

verworven luchtwegaandoeningen

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: acquired laryngeal stenosis, children, laryngotracheoplasty

Outcome measures

Primary outcome

To determine the quality of the voice, the Dysphonia Severity Index (DSI) will be done by speech pathologist M.H. Measurements for the following four parameters of the DSI will be obtained: highest fundamental frequency, lowest intensity, maximum phonation time and jitter.

To determine the physical strain, the following study parameters/ endpoints will be determined:

- Clinical history will be taken regarding complaints related to exercise capacity.

- Physical examination will be done; croupscore, growth and signs regarding physical strain will be determined.

- Fiberscopy will be done and recorded to visualize the anatomy and functionality of the larynx.

- Spirometry will be done and the forced vital capacity (FVC), forced expiratory volume in 1 second (FEV1), maximal flow at 25% of FVC remaining in the lung (FEF25%) and forced inspiratory volume in 1 second (FIV1) will be

measured.

- The Bruce treadmill test will be done. The maximal endurance time will be measured and serve as a criterion of exercise capacity. Before and during the test heart rate and transcutaneous oxygen saturation will be measured.
- The borgscore will be determined, a subjective measurement for the exercise capacity.
- An airway-resistance test will be performed to determine the resistance in the airway during expiration in kPa/L/s.

Secondary outcome

To determine the quality of life influenced by the quality of the voice, the Paediatric Voice Handicap Index (PVHI) or the Voice Handicap Index (VHI) will be used, depending on the age. The PVHI provides a measurement of the severity of a voice disorder in three domains: emotional, physical and functional. It provides the parents perception of the severity of the voice of his/ her son/ daughter and its impact on the daily life of their child.

To determine the health-related quality of life, the following validated questionnaires will be used, depending on the age: Child Health Questionnaire CHQ-CF87, Infant and Toddler Quality of Life Questionnaire ITQOL and Child Health Questionnaire - Parent Form 50 CHQ-PF50.

To determine self-esteem, the standardised and validated questionnaires *Self-Perception Profile for Children* (SPP-C), *Self-Perception Profile for Adolescents* (SPP-A) or *Nederlandse Persoonlijkheids Vragenlijst* (NPV-2) will

be used, depending on the age. Furthermore, the scar will be judged by the

children themselves and the physician, using a Visual Analog Score (VAS).

Study description

Background summary

Acquired laryngeal stenosis in children is a serious long-term complication of prolonged endotracheal intubation (>= 24h). In many children who develop a laryngeal stenosis, endoscopic treatment, a tracheostomy or laryngotracheal reconstruction is necessary. The goal of such surgery is to create an airway that is adequate for survival in the absence of a tracheostomy. However, an impaired quality of the voice, physical limitations as well as adverse psychological consequences are seen in this group of children who often have an extensive medical history, have had a tracheostomy for a long time before surgery and have had a laryngotracheal reconstruction.

Hypotheses
1. Infants and children after a laryngotracheal reconstruction or cricotracheal resection because of an acquired laryngeal stenosis, have
a. impaired quality of the voice
b. decreased physical strain
2. Infants and children after a laryngotracheal reconstruction or cricotracheal resection because of an acquired laryngeal stenosis, have
a. decreased quality of life caused by the impaired quality of the voice
b. decreased quality of life caused by the decreased physical strain
c. lower self-esteem because of the scar in the neck after tracheostomy and surgery

Study objective

Primary Objectives:
1. To determine the consequences in infants and children who had a laryngotracheal reconstruction or cricotracheal resection, regarding
a. quality of the voice
b. physical strain

Secondary objectives:
2. To determine the consequences in infants and children who had a laryngotracheal reconstruction or cricotracheal resection, regarding
a. quality of life influenced by quality of the voice
b. quality of life influenced by physical strain

c. self-esteem

Study design

The study is a descriptive cross-sectional study performed at the outpatient clinic at the Department of Otorhinolaryngology in the Sophia Children*s Hospital, Erasmus Medical Center, Rotterdam, the Netherlands.

Study burden and risks

Participating infants, children and their parents will receive an invitation for the outpatient clinic at the Department of Otorhinolaryngology in the Erasmus MC - Sophia Children*s Hospital.
First, they will be sent a covering letter, a patient information letter and an informed consent form. If informed consent is signed and send back, participating infants, children and their parents will receive an invitation for the outpatient clinic and several questionnaires. The parents of the children or children themselves, if they are capable and depending on the age, will be asked to fill out the questionnaires at home. The following research will be done at the outpatient clinic during their half day visit: clinical history, physical examination, fiberscopy, spirometry, treadmill test, determine borgscore, airway resistance and Dysphonia Severity Index. The regular follow-up of these children at the outpatient clinic varies between several times a year and no regular follow-up anymore.
Children might provide benefit from this study not only because of the thorough assessment of their health, but in addition they will be referred for further specialist care when needed. Furthermore, there are no serious adverse events associated with participation to the study.

Contacts

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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

Infants and children in whom prolonged intubation has caused a laryngeal stenosis and who had a laryngotracheal reconstruction or a cricotracheal resection at Sophia Children*s Hospital between 1994 and 2009. Informed consent has to be signed.

Exclusion criteria

Infants and children who had a laryngotracheal reconstruction or a cricotracheal resection because of a congenital laryngeal stenosis at Sophia Children*s Hospital.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-01-2011
Enrollment:	79
Type:	Actual

Ethics review

Approved WMO

Date:	30-11-2010
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	NL33690.078.10