Tracheomalacia in babies after correction of Esophageal Atresia - A First step to reduce respiratory morbidity

Published: 11-05-2023
Last updated: 07-04-2024

The main objective is to research the practicability of postoperative fLTB through the endotracheal tube, right before/during planned extubation in the intensive care unit (ICU) in newborn babies after EA correction.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal tract disorders congenital
Study type	Interventional

Summary

ID

NL-OMON53490

Source
ToetsingOnline

Brief title
Tracheomalacia after Esophageal Atresia Correction (TEA study)

Condition

- Gastrointestinal tract disorders congenital
- Gastrointestinal stenosis and obstruction
- Congenital respiratory tract disorders

Synonym
Congenital interrupted esophagus, esophageal atresia

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: Esophageal atresia, respiratory morbidity, tracheomalacia

Outcome measures

Primary outcome

The primary outcome parameter is the practicability of the fLTB, which will be determined by assessing the number of fLTB*s that could be completed and the number that were of sufficient quality for the otolaryngologists to assess the extent of TM. The fLTB will be deemed practicable if 7 out of 10 procedures (70%) were performed completely and were also of sufficient quality to be assessed systematically.

Secondary outcome

There are no secondary study parameters.

Study description

Background summary

After surgical correction of esophageal atresia (EA) weakening of the windpipe (or trachea), called tracheomalacia (TM), often occurs. TM can lead to a wide spectrum of respiratory morbidity. Severe TM is found in in up to 33% of EA patients. A rigid direct laryngeotracheobronchoscopy (dLTB) and flexible tracheobronchoscopy (fLTB) under general anesthesia are routinely performed prior to the correction of EA to assess the extent of the collapse and the presence of other possible concomitant airway anomalies. It is, however, not standard procedure to determine the severity of TM after the surgery. Current practice is a wait-and-see policy to determine if patients develop complaints of blue spells and recurrent respiratory infections. Then, patients will be brought to the operating room to evaluate the presence and degree of TM, after which treatment can be initiated. If it is practicable to evaluate the trachea for TM at an earlier stage, such as during planned extubation, then treatment for TM can be initiated at this earlier stage, before severe complaints occur

and/or before consequences of respiratory morbidity occur.

Study objective

The main objective is to research the practicability of postoperative fLTB through the endotracheal tube, right before/during planned extubation in the intensive care unit (ICU) in newborn babies after EA correction.

Study design

This study will be a multicenter, non-therapeutic, intervention study. After surgical repair of EA, a post-operative fLTB will be carried out right before/during planned extubation. The fLTB will be done through the endotracheal tube at the neonatal or pediatric ICU. The fLTB will be recorded for detailed assessment by two otolaryngologists. The practicability of this study intervention will be investigated by assessing if fLTB right before/during planned extubation can be performed completely and if TM can be assessed systematically.

Intervention

After surgical repair of EA, a post-operative fLTB will be carried out right before/during planned extubation. The fLTB will be done through the endotracheal tube at the neonatal or pediatric ICU.

Study burden and risks

After their surgical correction, the patient will undergo the postoperative fLTB during planned extubation, in the neonatal or pediatric ICU with local anaesthesia. The patient will be monitored carefully, as is routine during planned extubation. Although complications, such as laryngo- or bronchospasm and desaturations can occur, fLTB is at present a routine procedure pre-operatively and is associated with a low rate of complications in neonates. To reduce the risk of adverse events for the postoperative fLTB, a clinical assessment will be made prior to the procedure to evaluate if it is safe for a patient to undergo this procedure, otherwise the fLTB will not be performed. The goal of this study is to determine if it is doable to perform a fLTB through the endotracheal tube in the ICU to establish the presence of postoperative TM right before/during planned extubation so that the burden to the patient is minimized. In current practice, when an infant postoperatively develops symptoms of substantial TM (i.e. blue spells, recurrent respiratory tract infections), the infant is taken back to the operating room to undergo a rigid dLTB under general anesthesia. When TM is then established, treatment (mostly supportive, sometimes surgical) is commenced, but at that moment, possible adverse events may have already occurred. However, if it is doable to evaluate the trachea for TM at an earlier stage, such as right before/during

planned extubation, future studies could be designed with the aim to predict which patients will develop severe symptomatic TM.

In short, if postoperative fLTB is confirmed to be doable right before/during planned extubation in the ICU ward, this could benefit the EA patients because:
1. Minimizing burden: It is performed right before/during the already planned extubation (no need to return to the operating room for a rigid dLTB)
2. Possibly earlier start in treatment of severe TM (no wait-and-see policy to develop respiratory morbidity)
3. Possibly enable studies focussed on predicting which patients will develop severe TM by using the outcomes of the fLTB measurements before and after EA correction.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Newborns

Inclusion criteria

Patients with EA type C and D, Scheduled for surgical EA repair, Written informed consent by both parents or legal representative(s)

Exclusion criteria

Patients with EA types A, B and E, Endotracheal tube size < 3.0, Cormack score 3 or 4 as scored by either the otolaryngologist, anesthesiologist or neonatal/pediatric intensive care specialist, patients with a cyanotic cor vitium

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2023
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-05-2023
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL83362.000.23