Primary pOsterioR TRacheopexy prevents collapse of the trachea in newborns with esophageal AtresIa and Tracheomalacia

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

Summary

ID

NL-OMON56519

Source
ToetsingOnline

Brief title
Primary Posterior Tracheopexy prevents tracheal collapse

Condition

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

Synonym
collapse of the windpipe, Tracheomalacia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: For Wis(h)dom foundation

Intervention

Keyword: Esophageal atresia, primary posterior tracheopexy, respiratory morbidity, tracheomalacia

Outcome measures

Primary outcome

Primary endpoint:

The difference in the degree of tracheal collapse between the PPT and the

no-PPT group measured in percentage of the tracheal diameter, during:

- An intra-operative bronchoscopy after freeing the trachea and esophagus and,

in case of PPT-group, the PPT, but before the surgical correction of EA,

through the ventilation tube in the surgical theatre.

Secondary outcome

Key secondary endpoints:

The difference in the degree of tracheal collapse between the PPT and the

no-PPT group in percentages as measured during:

- a first postoperative bronchoscopy through the ventilation tube during

routine extubation in the pediatric or neonatal intensive care unit

- a second postoperative bronchoscopy that is conducted under general

anesthesia in the surgical theatre after approximately 2-6 months. This

bronchoscopy serves as a key secondary endpoint and aims to determine whether

the effect of PPT is sustained and/or if the TM deteriorates beyond the first

2 months.

Study description

Background summary

A blind-ending esophagus, or Esophageal Atresia (EA), is very often accompanied by a weakened windpipe (trachea). This is known as tracheomalacia (TM) and entails that the windpipe collapses during expiration. Severe TM can cause increased respiratory morbidity, including frequent respiratory tract infections and blue spells, that can potentially progress to respiratory arrest. Respiratory morbidity poses a significant burden on EA patients, both in the short term and over the course of long-term follow-up. When severe TM is identified, surgical intervention may be necessary. This surgical procedure involves widening the trachea (using sutures) to prevent its collapse, known as posterior tracheopexy (PT). Prior to performing this PT, complications and sequelae of TM may have already manifested. Additionally, performing this PT as a secondary operation after correcting the EA is a complex surgical procedure in newborns, and poses a significant risk of damaging the recently performed EA anastomosis. This separate, secondary PT also requires several hours of surgery, due to the presence of extensive adhesions. As a result, there has been a growing trend to carry out the PT concurrently with the initial correction of EA, known as a primary posterior tracheopexy (PPT). Previous studies have shown a decrease in respiratory tract infections (RTI*s) and brief respiratory unexplained events (BRUE*s) following the implementation of a PPT, when compared to patients who did not undergo PPT. However, it's important to note that these studies were predominantly conducted at a single medical center and relied mostly on retrospective data analysis To address several sources of bias, such as center-specific factors, selection-bias and information bias, a double-blind randomized controlled trial should be conducted.
To accurately evaluate the effects of PPT versus no-PPT (i.e. the tracheal diameter) a bronchoscopy needs to be performed, as it is the only objective measure for this purpose. Bronchoscopy allows for a direct visual examination of the trachea, ensuring a reliable and unbiased evaluation of the impact of PPT on tracheal diameter.

Study objective

The aim of this study is to evaluate if a PPT can significantly decrease - or possibly prevent - the collapse of the trachea in newborns with EA and moderate or severe TM. Additionally, the study aims to determine whether the observed effect of PPT on tracheal stability is sustained over time.

Study design

A double-blind randomized controlled trial

Intervention

randomization between performing a PPT or no-PPT

Study burden and risks

Burden:
To determine whether PPT is superior in preventing or reducing tracheal collapse, and subsequently respiratory morbidity, compared to no-PPT, a randomized double-blind trial is necessary.
This trial will eliminate dependence on other factors specific to individual centers and provide generalizable results. Importantly, since EA correction with PPT (more recently implemented in centers of expertise) and without PPT are both accepted and safe treatment options, participating in the trial does not pose an increased risk or burden for the participants with regards to the treatment. However, randomization of patients in this trial can be burdensome as it involves assigning them to either the PPT or no-PPT group based on chance. Parents/caretakers may have preferences or expectations regarding treatment, and being randomized to a specific group may not align with those preferences.
To address this burden, it is important to carefully explain the rationale and significance of randomization to the parents/caretakers. Providing clear and comprehensive information about the trial design, objectives, potential benefits, and the importance of unbiased evaluation can help alleviate concerns and ensure informed decision-making. Maintaining open communication channels and offering support throughout the trial can also help alleviate any emotional or psychological burden associated with the randomization process.

Performing intra- and postoperative bronchoscopies may pose a potential burden in the trial. However, a bronchoscopy is a routine diagnostic procedure commonly used to safely assess the condition of the trachea, even in newborns. Complications arising from bronchoscopy are rare. An intra-operative bronchoscopy through the ventilation tube is always performed in patients with a PPT as routine care. In patients with ventilatory problems, even without PPT, bronchoscopy can also be routinely performed. In this double-blind randomized trial, all patients will undergo the intra-operative flexible bronchoscopy through the ventilation tube. However, considering the controlled circumstances, there is negliglible burden and negliglible risk.
After the correction of esophageal atresia (EA), newborns are typically extubated in the neonatal or pediatric intensive care unit (ICU) within a few days. During this extubation process, the first postoperative bronchoscopy is conducted through the ventilation tube by a pediatric otorhinolaryngologist, with the presence of either the ICU specialist and ICU nurse. Therefore, the burden and risk associated with the bronchoscopy procedure are considered negligible, given the controlled and supervised environment it is performed. The duration of this bronchoscopy is 15 seconds.

The second postoperative bronchoscopy may present a burden due to the need for readmission and administration of general anesthesia in the operating theatre. However, a routine bronchoscopy in the surgical theatre is often performed in all (Karolinska Institutet and Great Ormond Street Hospital) or half (Wilhelmina and Sophia Children*s Hospital) of the EA patients, depending on the treating center. Thus, only in a small percentage of the trial participants an extra bronchoscopy is needed. Especially since the majority of these latter patients undergo a esophagogastroscopy under general anesthesia for clinical reasons (eg dilatation/eosinophilic esophagitis). In these patients the 2nd postoperative bronchoscopy will be performed during this planned esophagogastroscopy.The general anesthesia is administered to safely and effectively perform the bronchoscopy in a controlled and supervised environment. The bronchoscopy is the only objective measure to evaluate the degree of collapse in these patients. This second postoperative bronchoscopy will determine if the observed effect of the PPT on tracheal stability is sustained over time. Also, this burden is justifiable due to the potential deterioration of tracheal collapse that can occur in the first months following the initial EA correction. Conducting a second postoperative bronchoscopy allows for the identification of patients whose condition has worsened. The ability to identify such patients may outweigh the associated risks or added burden of the procedure in a small percentage of the trial participants. Moreover, if there is no difference between the intra-operative bronchoscopy and the first and second bronchoscopies, this could mean that in the future, we could sustain with only the (less burdensome) intra- (or first post-) operative bronchoscopy. The respiratory complaints will be evaluated to research if the degree of TM corresponds with the severity of the symptoms.

Group relatedness:
The advantage of conducting the primary posterior tracheopexy (PPT) earlier in the treatment process will become evident through the results of this randomized controlled trial (RCT). If PPT demonstrates superior outcomes, it could lead to a reduction in postoperative complications and interventions, including bronchoscopies under general anesthesia and additional extensive surgeries for secondary PPT. Conversely, if the secondary posterior tracheopexy (PT) yields better results, it could mean fewer babies having to undergo an unnecessary PPT procedure. The trial will provide valuable insights to guide the optimal timing for tracheopexy and approach of tracheomalacia in improving patient outcomes/symptoms.
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Babies and toddlers (28 days-23 months)
Newborns
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

Patients with esophageal atresia type with a distal tracheoesophageal fistula (TEF), with tracheomalacia, written informed consent by both parent(s) or legal representative(s).

Exclusion criteria

Patients with esophageal atresia without a distal TEF, premature neonates <34 weeks, 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
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2024
Enrollment:	45
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	31-01-2024
Application type:	First submission
Review commission:	METC NedMec

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	NL84862.041.24