Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of delayed primary esophageal anastomosis in patients with long gap esophageal atresia with primary esophageal replacement by gastric pull up sugery.

Protocol summary

Study aim

Comparison of two methods in treatment of long gap esophageal atresia: delayed esophageal repair by primary anastomosis and neonatal esophageal replacement by gastric pull-up.

Design

In this study, infants with rare esophageal atresia without fistulas were compared in terms of type and timing of surgical intervention in two groups :delayed repair and replacement in infancy.This Clinical trial is designed without control group, with parallel groups, without blinding, randomized, phase 2 on 20 patients. Excel software rand function was used for randomization.

Settings and conduct

Due to the challenge in treating long-gap esophageal atresia، Infants who are referred to Tabriz Children's Hospital with diagnosis of esophageal atresia were examined by thoracoabdomen X-ray and considered type A cases if gas is not seen in the stomach.They enter the study with parent's consent. After assignment to study groups, group 1, undergoes gastrostomy and care for delayed repair, and if the gap is reduced, a primary anastomosis is performed. Group 2 undergoes esophageal replacement by gastric pull-up in infancy. Treatment outcomes, complications and mortality are compared in the two groups. As caregivers and parents are aware of the type of intervention due to the difference in medical care, it was not possible to blind this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria:neonates with long gap esophageal atresia and without fistula Exclusion criteria: neonates with unstable general conditions which were expired before surgery neonates with severe associated anomalies and high risk for surgery.

Intervention groups

1st G:primary gastrostomy and delayed esophageal repair 2nd G:esophageal replacement by gastric pull up

Main outcome variables

complication including pre- peri-and post-operative complications. Possibility of preserving the patient's esophagus Mortality rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210518051337N1**
Registration date: **2021-12-27, 1400/10/06**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-27, 1400/10/06**
Update count: **0**

Registration date

2021-12-27, 1400/10/06

Registrant information

Name

Nazila Hasanzadeh Ghavifekr

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-06, 1400/09/15

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of delayed primary esophageal anastomosis in patients with long gap esophageal atresia with primary esophageal replacement by gastric pull up sugery.

Public title
Comparison of delayed primary esophageal repair in patients with long gap esophageal atresia with primary esophageal replacement.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Long gap congenital esophageal atresia
Exclusion criteria:
presence of gastric air in postnatal x-ray prior esophagostomy before enterance to study suspicious upper pouch fistula Other severe congenital anomalies with unstable general condition
Age
To **5 days** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Among neonates with esophageal atresia without fistula who have the inclusion criterias to enter the study, all patients with parental consent are admitted to the study in non-randomly manner. Then random division is done between study groups. In this study, a simple random allocation method using the RandList 1.2 function of Excel software is used as a tool for randomization. 1 group of delayed treatment and 2 group of neonatal surgery.In the randomization process for allocation concealment.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Tabriz University of Medical Sciences Evaluated by: Ap
Street address
Tabriz University of Medical Sciences., Golgasht St., Azadi St
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East Azarbaijan
Postal code
5166614766
Approval date
2021-11-29, 1400/09/08
Ethics committee reference number
IR.TBZMED.REC.1400.858

Health conditions studied

1

Description of health condition studied
esophgeal atresia without fistula
ICD-10 code
Q39.1
ICD-10 code description
Atresia of esophagus without tracheo-esophageal fistula

Primary outcomes

1

Description
decrease of the gap between upper and lower pouch os esophagus
Timepoint
initially two weeks after birth and then continuously every 20 days
Method of measurement
measurement of distance between upper and lower pouch of esophagus with opaque bogie under anesthesia and evaluation of therapeutic result and complications with checklist.

2

Description
short term and long term complicayions of surgery
Timepoint
during operation, inthe post operation period, 2 month later, 4 month later
Method of measurement
clinical and radiologic signs of complications such as anastomosis leak, pneumonia, sepsis, stricture and reflux.

Secondary outcomes

1

Description
the ability to save and reconstruct the own esophagus of patient
Timepoint
n the operative procedure
Method of measurement
the operation Feasibility

Intervention groups

1

Description
Intervention group: delayed repair by primary anastomosis The first group received delayed intervention.the newborns with type A LGEA, the first surgical intervention was placement of gastrostomy tube through an open surgery. A tube was used as the gastrostomy and in order to prevent aspiration, proximal pouch of the esophagus was repeatedly suctioned via a nasogastric or orogastric tube. Twenty days after the gastrotomy, an esophagoscope or bogie was inserted through the proximal pouch of esophagus and a bougie was inserted into the distal pouch of esophagus via gasterostomy, afterwards, the gap length between the proximal and distal esophageal pouch was measured by taking a radiograph. If the gap length was less than 2 cm, a primary esophageal anastomosis was performed immediately through right posterolateral thoracotomy. However, if the gap length was more than 2 cm, watchful waiting would have been continued and evaluation of the gap length was delayed for 20-30 days later. Esophageal reconstruction was delayed until the proper gap length was achieved. In first 3 months after birth, if there were any evidences of development and the gap length decrease to less than 2 cm (or less than the length of two vertebral bodies), delayed esophageal anastomosis was performed. Outcomes of this procedure was then evaluated considering the side effects such as pulmonary infections and sepsis occurring during the watchful waiting. The watchful waiting of the infant was done for 4 months after the esophageal reconstruction.
Category
Treatment - Surgery

2

Description
Control group: Gastric pull-up surgery in the neonatal period. The second group received primary intervention. In this group, in order to replace a section of underdeveloped esophagus with reconstructed stomach tissue, gastric pull up surgery was performed by the midline lapatomy and release of gastric tissue in the base of right gastric and gastroepipoloic arteries and gastric pull-up through the hiatus diapgragm and anastomosis through the right sided neck or right thorax cavity to the proximal pouch of esophgus. After the surgery, parenteral feeding was done until the patient was able to tolerate normal oral diet.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Children's Hospital
Full name of responsible person
Saed Aslanabadi
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences

Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Position
subspeciality resident of pediatric surgery, general surgeon
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available