

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 surgery.

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

Country

Iran (Islamic Republic of)

Phone

+98 41 3385 1683

Email address

nazila.hasanzadeh@gmail.com

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 surgery.

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 entrance 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

City

Tabriz

Province

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 diaphragm and anastomosis through the right sided neck or right thorax cavity to the proximal pouch of esophagus. 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

Street address

sheshgelan St. Tabriz children's hospital

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Phone

+98 41 3526 2250

Fax

+98 41 3526 2279

Email

nazila.hasanzadeh@gmail.com

Web page address

<https://childrenhospital.tbzmed.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Saeid Aslanabadi

Street address

East Azerbaijan, Tabriz , GholGhasht St. Tabriz university of medical sciences.

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Phone

+98 41 3335 5921

Email

info@tbzmed.ac.ir

Web page address

<https://Tbzmed.ac.ir>

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

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Phone

+98 41 3526 2250

Email

aslanabadis@hotmail.com

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

nazila Hasan zadeh Ghavifekr

Position

subspeciality resident of pediatric surgery, general surgeon

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Gholshar- Ghole yakh st. 22

City

Tabriz

Province

East Azarbaijan

Postal code

5167858549

Phone

+98 41 3385 1683

Email

nazila.hasanzadeh@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

nazila Hasan zadeh Ghavifekr

Position

subspeciality resident of pediatric surgery, general surgeon

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Gholshar- Ghole yakh st. 22

City

Tabriz

Province

East Azarbaijan

Postal code

5167858549

Phone

+98 41 3385 1683

Email

nazila.hasanzadeh@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Saeid AslanAbadi

Position

professor of pediatric surgery

Latest degree

Subspecialist

Other areas of specialty/work

pediatric surgery

Street address

sheshgelan st. Tabriz childrens' Hospital

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