

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Evaluation of Azygos vein preservation Necessary in Primary Repair of Trachea esophageal Fistula with Esophageal Atresia

Protocol summary

Study aim

The aim of this study was to evaluate the effectiveness of Azygos vein occlusion in patients with Tracheoesophageal fistula and Esophageal atresia.

Design

Clinical trial with control group and a parallel group without blind strain randomized on 40 patients. For randomization, 4-way permutation block method was used.

Settings and conduct

This was a clinical trial conducted on neonates with esophageal atresia and Tracheoesophageal fistula in Imam Khomeini Hospital in Ahvaz.

Participants/Inclusion and exclusion criteria

Neonates with Tracheoesophageal fistula and Esophageal atresia

Intervention groups

- 1.Tracheoesophageal fistula and Esophageal atresia repair with occlusion of the azygos vein.
- 2.Tracheoesophageal fistula and Esophageal atresia repair with preservation of the azygos vein.

Main outcome variables

At the beginning of the study, age, gender, weight, anomalies associated with Esophageal atresia of all neonates were recorded, then, all neonates were randomly divided into two equal groups. In one group, Esophageal atresia is repaired with azygos vein ligate and in the other group Esophageal atresia repaired with azygos vein preservation. In this study, duration of surgery, rate of pneumonia, existence of anastomosis leak, stenosis at the site of anastomosis and mortality rate between the two groups of neonates were investigated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201012049012N1**

Registration date: **2020-11-20, 1399/08/30**

Registration timing: **retrospective**

Last update: **2020-11-20, 1399/08/30**

Update count: **0**

Registration date

2020-11-20, 1399/08/30

Registrant information

Name

behruz shayestezadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3336 3238

Email address

behruz.shayestezadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-24, 1398/02/04

Expected recruitment end date

2019-08-26, 1398/06/04

Actual recruitment start date

2019-04-24, 1398/02/04

Actual recruitment end date

2019-08-26, 1398/06/04

Trial completion date

2019-08-26, 1398/06/04

Scientific title

Evaluation of Azygos vein preservation Necessary in Primary Repair of Trachea esophageal Fistula with Esophageal Atresia

Public title

Azygos vein in Esophageal Atresia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 neonates with Trachea esophageal Fistula with Esophageal Atresia
Exclusion criteria:

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
 Target sample size: **20**
 Actual sample size reached: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
 Neonates with a diagnosis of tracheoesophageal fistula with esophageal atresia who matched our diagnostic criteria will be selected to participate in the study. There will be randomly subdivided them in to Two group ' first whom which their Esophageal atresia will get treated with closure of azygous vein ' second whom which their Esophageal atresia will get treated with preserving the azygos vein. randomization will be simple and individual.

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
 Ethics committee of Jondishapur university of medical sciences
Street address
 Jundishapur university of medical sciences, Golestan street, Ahvaz, Iran
City
 Ahvaz
Province
 Khuzestan
Postal code
 6135715794
Approval date
 2018-04-21, 1397/02/01

Ethics committee reference number
 IR.AJUMS.REC.1397.011

Health conditions studied

1

Description of health condition studied
 Tracheoesophageal fistula with Esophageal atresia
ICD-10 code
 Q39.1
ICD-10 code description
 Tracheoesophageal fistula with Esophageal atresia

Primary outcomes

1

Description
 Pneumonia
Timepoint
 Evidence of pneumonia was investigated before surgery one week and one month after surgery.
Method of measurement
 Clinical examination and laboratory evidence.

2

Description
 Anastomosis leak
Timepoint
 Daily after surgery until the patient's PO tolerance and discharge
Method of measurement
 Clinical examinations and laboratory evidence

3

Description
 duration of surgery
Timepoint
 Based on hours after surgery
Method of measurement
 Based on hours after surgery

4

Description
 Stenosis of the place of anastomosis
Timepoint
 After patient po
Method of measurement
 by radiography and clinical examination

5

Description
 Blood transfusion rate
Timepoint
 From surgery to patient discharge
Method of measurement
 by pack cell transfusion rate

6

Description

length of hospital stay

Timepoint

From surgery to patient discharge

Method of measurement

based on days of stay

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Neonates which Esophageal atresia and Tracheoesophageal fistula repaired with azygos vein ligation.

Category

Treatment - Surgery

2

Description

Intervention group: Neonates which Esophageal atresia and Tracheoesophageal fistula repaired with preserving the Azygos vein.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital

Full name of responsible person

dr.shahnam asgarpour

Street address

Imam khomeini hospital, Azadegan street, Ahvaz

City

ahvaz

Province

Khouzestan

Postal code

6193673111

Phone

+98 61 3222 2085

Email

behruz.shayestezadeh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

dr.shahnam asgarpour

Street address

4th floor, 52 Elham ave, Kianpars street, Ahvaz, Iran

City

Ahvaz

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Postal code

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Phone

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Email

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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

Ahvaz 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

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

dr. shahnam asgarpour

Position

professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatric Surgery Specialist

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Person responsible for scientific

inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The whole data is listed randomly and without personal information.

When the data will become available and for how long

No time limits

To whom data/document is available

No limits

Under which criteria data/document could be used

No limits

From where data/document is obtainable

Jundishapor university of medical science

What processes are involved for a request to access data/document

Data can be accessed by connecting to the article organizer email and contacting Imam Khomeini Hospital in Ahvaz

Comments