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)
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+98 61 3336 3238
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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

Khouzestan

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
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Postal code
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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
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behruz.shayestezadeh@gmail.com
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
Street address
4th floor, 52 Elham ave, kianpars street, Ahvaz, Iran
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Person responsible for scientific

inquiries

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Ahvaz University of Medical Sciences

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Person responsible for updating data

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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