

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparative survey of incidence of postoperative complications in patients with esophageal atresia repaired with absorbable and nonabsorbable sutures

Protocol summary

Summary

The purpose of this study is to compare the prevalence of postoperative complications in patients with esophageal atresia repaired with absorbable and nonabsorbable sutures. This study is a non-blinded clinical trial. 36 patients with esophageal atresia referred to Emam Reza and Mohammad Kermanshah hospitals were selected using an accessible sampling method and randomly divided into two intervention groups. The first intervention group underwent anastomosis with non-absorbable silk sutures, and the second intervention group underwent anastomosis with absorbable Vicryl sutures. Both groups were followed up for 48 hours, 5 days, 7 days, and one year after surgery. The primary outcome was the rate of anastomosis leakage, and secondary outcomes included mortality rate, average hospital stay, and average hospitalization cost. Inclusion criteria: patients diagnosed with esophageal atresia according to radiology and clinical evidence and who are candidates for surgery. Exclusion criteria: patients with a space within the stomach of the esophagus more than 3 cm that has a direct effect on the prevalence of postoperative complications in anastomosis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013101414333N11**
Registration date: **2013-10-26, 1392/08/04**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-10-26, 1392/08/04

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-11-21, 1392/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative survey of incidence of postoperative complications in patients with esophageal atresia repaired with absorbable and nonabsorbable sutures

Public title

Comparative survey of incidence of postoperative complications in patients with esophageal atresia repaired with absorbable and nonabsorbable sutures

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: those who diagnosed afflicted to Esophagus Atresia according to radiology and clinical evidence and they are candidate for surgery .exclusion criteria:the space within towheaded of Esophagus is more than 3 cm that has direct effect to prevalence of postoperative complications in Anastomose place

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

N/A

Randomization description**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**

Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code**Approval date**

2013-07-20, 1392/04/29

Ethics committee reference number

16065/7/420/پ

Health conditions studied**1****Description of health condition studied**

Esophageal Atresia

ICD-10 code

Q39.1

ICD-10 code description

Atresia of oesophagus with tracheo-oesophageal fistula

Primary outcomes**1****Description**

rate of Anastomosis Leakage

Timepoint

First 48 hours, 5-7 day after surgery

Method of measurement

Clinical And Radiology evidence

2**Description**

Anastomosis Stricture

Timepoint

One year After Surgery

Method of measurement

Clinical And Radiology evidence

3**Description**

Mortality Rate

Timepoint

One year After Surgery

Method of measurement

Patient Case

4**Description**

Time average Stay in Hospital

Timepoint

One year After Surgery

Method of measurement

Patient case

5**Description**

Hospitalization Cost Average

Timepoint

One year After Surgery

Method of measurement

patient case

Secondary outcomes

empty

Intervention groups**1****Description**

In the first intervention group, Anastomosis do with non absorbable silk sutures

Category

Treatment - Surgery

2

Description

in the second intervention group, Anastomosis do with absorbable vicrel sutures

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr. Mohamadreza Namdari

Street address

Emam Reza Hospital,Razi Boulevard,Sorkhleje

City

Kermanshah

2

Recruitment center

Name of recruitment center

Mohamad Kermanshahi Hospital

Full name of responsible person

Dr. Mohamadreza Namdari

Street address

Mohamad Kermanshahi Hospital,Chaharrahe Helal Ahmar,Mosavari Street

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Omid Amanollahi

Position

Pediatric Surgeon

Other areas of specialty/work

Street address

Emam Reza Hospital,Razi Boulevard,Sorkhleje

City

Kermanshah

Postal code

Phone

+98 83 1427 6309

Fax

Email

oamanollahi@yahoo.com

Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty