

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of two methods of surgery(transpleural and extrapleural)in treatment of esophageal atresia in neonates .

Protocol summary

Summary

The treatment of esophageal atresia is performed by two different methods that can be used in neonates, a procedure without opening the pleura (extrapleural route) and another method with opening the pleura (Trans plural). Comparison of these methods can be useful for surgeons to choose the best method for esophageal atresia repair with fewer mortality and complications. Comparison of surgical treatment of esophageal atresia in infants Trans plural and extrapleural is the aim of recent trial. Methods: In this project we divide all neonates who have esophageal atresia(type-c) to 2 group; in the study group surgery is done without entrance to pleural space(extrapleural) and in the control, surgery is done Trans plural (by opening the pleura). Comparison of two methods for mortality and complications help us to choose the best method of repair. Most important benefit of this research is to increase patients' survival and can reduce the mortality and reduce suffering of patients and their parents due to complications or recurrences.

General information

Acronym

Transpleural and extrapleural surgery in esophageal atresia

IRCT registration information

IRCT registration number: **IRCT201301315966N1**
Registration date: **2013-05-03, 1392/02/13**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-03, 1392/02/13

Registrant information

Name

Omid Amanollahi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

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+98 988314276310

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

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

Comparison of two methods of surgery(transpleural and extrapleural)in treatment of esophageal atresia in neonates .

Public title

Comparison of two methods of surgery(transpleural and extrapleural)in treatment of esophageal atresia in neonates .

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: cases of esophageal atresia(common type)who underwent thoracotomy for repair. Exclusion criteria: any risk factor that affect surgical result, like low

birth weight(under2kg). severe pulmonary infection, major cardiopulmonary problems, long gap atresia; any untoward problems unrelated to surgical technique that can affect surgical results.

Age

To **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

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

shahid beheshti av.-research center of university

City

kermanshah

Postal code

6714869914714869914

Approval date

2012-11-20, 1391/08/30

Ethics committee reference number

/7/420/پ

2

Ethics committee

Name of ethics committee

kermanshah university of medical sciences

Street address

shahi beheshthi street. research center

City

kermanshah

Postal code

6714869914714869914

Approval date

2012-11-20, 1391/08/30

Ethics committee reference number

/7/420/پ

Health conditions studied

1

Description of health condition studied

Esophageal atresia with tracheoesophagofistula. fistula

ICD-10 code

Q39-1

ICD-10 code description

Atresia of oesophagus with tracheo-oesophageal fistula

Primary outcomes

1

Description

Mortality

Timepoint

1 month

Method of measurement

Counting of mortality cases

Secondary outcomes

1

Description

Increase of survival

Timepoint

1 month

Method of measurement

Counting of survived cases

Intervention groups

1

Description

Surgery has been done extrapleural in study group (esophagus exposed without entrance to pleural space.

Category

Treatment - Surgery

2

Description

Surgery is intrapleural and esophagus exposes by entrance to pleural space in control group.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammad Kermanshahi hospital

Full name of responsible person

Dr. Omid Amanollahi

Street address

Mohammad Kermanshahi hospital, Helal Ahmar cross

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Research center- 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

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

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Omid Amanollahi

Position

Assistant professor of pediatric surgery

Other areas of specialty/work

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Name of organization / entity

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Position

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Other areas of specialty/work

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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