

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### To determine the effectiveness of clinical outcomes of early nutritional support at infant with esophageal atresia

#### Protocol summary

##### Summary

Purpose of the study: To determine the effectiveness of clinical outcomes of early nutritional support at infant with esophageal atresia. A not blind, block randomized clinical trial. Study population: Infants with esophageal atresia who will have surgical repair at doctor Sheikh Hospital. Inclusion criteria: Children with esophageal atresia type C; gestational age over 34 weeks; not have other major abnormalities addition of atresia; in the first group classification of spitz; distance less than 3 cm between two blind bags in atresia; weighing patients over 1800 grams; children have physiological stability. Exclusion criteria: Dependence on the ventilator and delayed weaning from mechanical ventilation for more than 48 hours; clinical symptoms of Anastomotic leakage in the first 48 hours after surgery. Sample size: 36 cases. Study intervention: Feeding 48 hours after surgical repair of esophageal atresia. Intervention time: 48 hours after surgical repair of esophageal atresia. The outcome of the study: To determine the effectiveness of early feeding on feeding tolerance, length of hospitalized, Anastomotic stricture, Anastomotic leakage and weighting to improve at groups cases.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015110524893N1**

Registration date: **2016-05-02, 1395/02/13**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-05-02, 1395/02/13

##### Registrant information

##### Name

marzieh ghorbani

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3753 4374

##### Email address

ghorbanim8@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

##### Expected recruitment start date

2016-05-21, 1395/03/01

##### Expected recruitment end date

2016-12-21, 1395/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

To determine the effectiveness of clinical outcomes of early nutritional support at infant with esophageal atresia

##### Public title

Effectiveness of early nutrition in infants with esophageal atresia

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Children with esophageal atresia type C; gestational age over 34 weeks; not have other major abnormalities addition of atresia; in the first group

classification of spitz; distance less than 3 cm between two blind bags in atresia; weighing patients over 1800 grams; children have physiological stability. Exclusion criteria: Dependence on the ventilator and delayed weaning from mechanical ventilation for more than 48 hours; clinical symptoms of Anastomotic leakage in the first 48 hours after surgery.

#### Age

To 28 days old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 36

#### Randomization (investigator's opinion)

Randomized

#### 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

Ethics Committee of Mashhad University of Medical Sciences

##### Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

##### City

Mashhad

##### Postal code

99191-91778

#### Approval date

2015-07-04, 1394/04/13

#### Ethics committee reference number

IR.MUMS.REC.1394.246

## Health conditions studied

### 1

#### Description of health condition studied

Esophageal atresia

#### ICD-10 code

Q39.1

#### ICD-10 code description

آنرزی مری با فیستول تراشه

## Primary outcomes

### 1

#### Description

length of hospitalized

#### Timepoint

After intervention until discharge from hospital

#### Method of measurement

Questionnaire

### 2

#### Description

Anastomotic leakage

#### Timepoint

After intervention until discharge from hospital

#### Method of measurement

X-ray

### 3

#### Description

weighting to improve

#### Timepoint

After intervention until one month after discharge from hospital

#### Method of measurement

Balance

### 4

#### Description

Feeding tolerance

#### Timepoint

After the intervention, one month after discharge from hospital

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

Anastomotic stricture

#### Timepoint

One month after discharge from hospital

#### Method of measurement

Endoscopy

## Intervention groups

### 1

#### Description

Feeding 48 hours after surgical repair of esophageal atresia

**Category**

Other

**2****Description**

The control group: Did not do anything

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Doctor Sheikh Hospital

**Full name of responsible person**

Gholamreza khademi

**Street address**

Doctor Sheikh Hospital, Manoochehri

**City**

Mashhad

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**Vice Chancellor for Research, Mashhad University of  
Medical Sciences, Ghoreishi building, Daneshgah  
Street**City**

Mashhad

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Akram Rezaeian

**Position**

Master of Pediatric Nursing

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**Position**

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Mashhad University of Medical Sciences

**Full name of responsible person**

Marzieh Ghorbani

**Position**

Master of Neonatal Nursing

**Other areas of specialty/work****Street address**

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**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Statistical Analysis Plan**

**Data Dictionary**

*empty*