Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 over1800 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

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Name of organization / entity

Mashhad University of Medical Sciences

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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 over1800 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
آترزی 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
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Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
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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
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
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ghorbanim8@mums.ac.ir

Web page address

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