

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Clinical trial of comparison of effectiveness of proximal to anastomosis T-tube enterostomy versus conventional end to end anastomosis in treatment of neonates with intestinal atresia

Protocol summary

Study aim

Clinical trial of comparison of effectiveness of proximal to anastomosis T-tube enterostomy versus conventional end to end anastomosis in treatment of neonates with intestinal atresia

Design

Randomized, parallel group trial. Randomization was centralized with simple randomization with random allocation rule

Settings and conduct

Fifty six neonates with intestinal atresia referred to Ahvaz Imam Khomeini Hospital will be studied. Primary diagnosis will be based on the abdominal distension, absence of meconium excretion, bilious vomiting, Oral intolerance and radiological findings

Participants/Inclusion and exclusion criteria

An inclusion criterion is neonates with intestinal atresia based on the clinical signs and radiographic assessment; The exclusion criterion is neonates with diagnosis of a complication than intestinal atresia

Intervention groups

Fifty six neonates with intestinal atresia will be divided into two comparable groups. In the first group, proximal to anastomosis T-tube enterostomy is performed. In the second group, only conventional end to end anastomosis is performed

Main outcome variables

Interval between surgery and beginning of oral nutrition;
Rate of anastomotic leak; Rate of anastomotic stricture;
Peritonitis rate after surgery; Duration of improvement of T-tube placement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180811040765N1**

Registration date: **2018-08-17, 1397/05/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-17, 1397/05/26**

Update count: **0**

Registration date

2018-08-17, 1397/05/26

Registrant information

Name

Hoda Ilkhani Pak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 2925

Email address

ilkhani.h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-06, 1397/05/15

Expected recruitment end date

2018-11-06, 1397/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison of effectiveness of proximal to anastomosis T-tube enterostomy versus conventional end to end anastomosis in treatment of neonates with

intestinal atresia

Public title
Comparison of efficacy of proximal to anastomosis T-tube enterostomy versus conventional end to end anastomosis in neonates with intestinal atresia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Neonates with primary diagnosis of intestinal atresia according to the clinical signs and radiographic assessment
Exclusion criteria:
Diagnosis of a complication than atresia after initial evaluations

Age
From **1 day** old to **20 days** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization with random allocation rule: First the sample size was calculated. Then, the subjects (n=56) are randomly assigned into two groups of intervention and control (each 28). In the random assignment, 28 cards are assigned to intervention and 28 to control group. The cards are randomly and without replacement removed from the box and the sequence is recorded.

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 Ahvaz University of Medical Sciences
Street address
Golestan Blvd., Research deputy, Ahvaz Jundishapur University Of Medical Sciences
City

Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2017-12-16, 1396/09/25
Ethics committee reference number
IR.AJUMS.REC.1396.1068

Health conditions studied

1

Description of health condition studied
Intestinal Atresia
ICD-10 code
Q41
ICD-10 code description
Congenital absence, atresia and stenosis of small intestine

Primary outcomes

1

Description
Interval between surgery and beginning of oral nutrition
Timepoint
The first day of neonatal oral tolerance
Method of measurement
Daily examinations

2

Description
Rate of anastomotic leak
Timepoint
During hospitalization stay
Method of measurement
Sonographic diagnosis

3

Description
Rate of anastomotic stricture
Timepoint
During hospitalization stay
Method of measurement
Imaging findings

4

Description
Peritonitis rate after surgery
Timepoint
Daily examinations and evaluations
Method of measurement
Clinical signs and blood test

5

Description

Duration of improvement of T-tube placement

Timepoint

On the 3, 5, 7 and 14 days after discharge

Method of measurement

Outpatient examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Primary end-to-end anastomosis with T-tube application

Category

Treatment - Surgery

2

Description

Control group: Only primary end-to-end anastomosis

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Shahnam Askarpour

Street address

Azadegan Ave., Imam Khomeini Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi, PhD

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Grant name

Grant code / Reference number

33012192

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

Hoda Ilkhani Pak

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

Shahnam Askarpour

Position

Associate professor

Latest degree

Subspecialist

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Person responsible for updating data

Contact

Name of organization / entity

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Position

Resident

Latest degree

Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable