

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Comparative study of the results of colostomy closure with purse-string and linear methods in pediatric patients

Protocol summary

Study aim

Comparison of results of colostomy closure by purse-string and linear methods in children

Design

Clinical trial with intervention and control groups, 100 patients sample size, Trial phase 2-3. Simple randomization based on random numbers table.

Settings and conduct

100 patients with intestinal colostomy who met inclusion criteria among candidates referred to Imam Khomeini and Golestan hospitals in 2017-2019 were divided to control or intervention groups. In intervention group, the skin was closed by purse-string method include an incision around the ileostomy. In control group, the skin was closed to the ileum by an elliptical incision around the colostoma.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages 0-6 years ; Reversible loop ileostomy ; Elective closure of colostomy ; Parent consent for their child participation in the project
Exclusion criteria: Death; Patient failure to cooperate during follow-up; The existence of a new stoma at the time of study; Speech problems and mental disorders.

Intervention groups

Intervention group: In this group the skin was closed by purse-string method include an incision around the ileostomy that was similar to the linear method. But the cut was roughly split using a sub-cuticle rope (2-0 Polysorb). Control group: In this group, closure of the skin was done by an elliptical incision around the colostoma to the ileum, fascia then the skin was sutured.

Main outcome variables

Duration of wound healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121010011068N3**

Registration date: **2019-12-07, 1398/09/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-07, 1398/09/16**

Update count: **0**

Registration date

2019-12-07, 1398/09/16

Registrant information

Name

Shahnam Askarpour

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3338 0656

Email address

shahnam_askarpour@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-31, 1398/08/09

Expected recruitment end date

2019-12-20, 1398/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the results of colostomy closure with purse-string and linear methods in pediatric patients

Public title

Comparative treatment results of colostomy closure with purse-string and linear methods in pediatric patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 0-6 years Reversible loop ileostomy Candidate for elective closure of ileostomy Parents' consent

Exclusion criteria:

Age more than 6 years Death Patient failure to cooperate during follow-up The existence of a new stoma at the time of study Speech problems and mental disorders

Age

To **6 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization based on random numbers table, in this method, we set a set of numbers without a specific pattern and order, and completely randomly in the table. We consider the even numbers as intervention group and the odd numbers as control group. Then accidentally put the finger on one of the numbers in table and then move upwards, register the number and assign one to an intervention or control group.

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 Jundishapur University of Medical Sciences

Street address

Vice Chancellor for Research and Technology Ahvaz Jundishapur University of Medical Sciences, University City

City

Ahvaz

Province

Khuzestan

Postal code

15794-61357

Approval date

2019-04-30, 1398/02/10

Ethics committee reference number

IR.AJUMS.REC.1398.009

Health conditions studied

1

Description of health condition studied

Closestomy closure

ICD-10 code

Z43.3

ICD-10 code description

Encounter for attention to colostomy

Primary outcomes

1

Description

Duration of wound healing

Timepoint

postoperatedays 1, 2 and 3, at the hospital discharge, and 30 days, 6 and 12 months after surgery.

Method of measurement

Observation and examination by a physician

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group the skin is closed by purse-string method includes an incision around the ileostomy that is similar to the linear method. But the cut is roughly split using a sub-cuticle rope (2-0 Polysorb).

Category

Treatment - Surgery

2

Description

Control group: In this group, skin closure involves an elliptical incision around the Colostoma to the ileum and fascia is sutured then the skin is sutured with artificial suture.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini Hospital
Full name of responsible person
Shahnam Askarpour MD.
Street address
Azadegan St.
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shahnam_askarpour@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badvi P.H.D
Street address
Vice Chancellor for Research and Technology Ahvaz
Jundishapur University of Medical Sciences, University
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vchresearch@ajums.ac.ir
Grant name
Grant code / Reference number
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
Shahnam Askarpour MD.
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The whole data can be shared after unidentifiable people.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Only available to scholars working in academic and academic institutions

Under which criteria data/document could be used

Employed in research centers

From where data/document is obtainable

Person responsible for scientific inquiries

What processes are involved for a request to access data/document

Send email to person responsible for scientific inquiries

Comments