

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the results of using the ERAS protocol in the process of recovery of children in need of colostomy reversal referred to Isfahan

Protocol summary

Study aim

Evaluation of the results of using the ERAS protocol in the process of recovery of children in need of colostomy

Design

This study is a non-blinded, randomized clinical trial with a parallel design. This randomized study will be conducted on 86 children who are eligible for surgery. A random block is used for randomization and the participants are assigned to two intervention groups.

Settings and conduct

This study will be conducted in Imam Hossein Hospital in Isfahan city. Patients in both groups are fasting from 12:00 PM the night before the operation, and no painkillers are prescribed before the operation. In both groups, the type and method of surgery are the same and the same surgeon performs it. Therefore, the surgery should be performed for both groups, encouraging spirometry and respiratory physiotherapy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 1 day and 15 years;
Patients who are candidates for colostomy surgery;
Consent of patients or their parents
Exclusion criteria:
Underlying disease that leads to tissue repair impairments (such as severe malnutrition or connective tissue disease)

Intervention groups

In the first intervention group (traditional protocol), the patient remains fasting for 5 days after the operation, and we prescribe albumin, vitamins and carbohydrates (dextrose serum) for the patient, and put him under intravenous nutrition, and the diet does not start earlier than 5 days. In the second intervention group (ERAS), usually 24 to 48 hours after the operation, depending on when the patient defecates, we start the liquid diet for the patient and do not put the patients under intravenous nutrition.

Main outcome variables

recovery process, wound infection, re-hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N212**

Registration date: **2023-12-12, 1402/09/21**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-12, 1402/09/21**

Update count: **0**

Registration date

2023-12-12, 1402/09/21

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 83 1821 4653

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-11, 1402/09/20

Expected recruitment end date

2025-03-10, 1403/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the results of using the ERAS protocol in the process of recovery of children in need of colostomy reversal referred to Isfahan

Public title

Evaluation of the results of using the ERAS protocol in the process of recovery of children in need of colostomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 1 day and 15 years Patients who are candidates for colostomy surgery Consent of patients or their parents

Exclusion criteria:

Underlying disease that leads to tissue repair impairments (such as severe malnutrition or connective tissue disease)

Age

From **1 day** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization using the blocking method with blocks in sizes 6 and 9. For randomization, the site <https://www.sealedenvelope.com> is used. All codes are recorded on paper and stored in specific envelopes. Each of the generated codes is kept separately inside the envelope and the secretary gives one of these envelopes to the patient before the patient enters the doctor's room. Accordingly, the next patient code is not predictable. The doctor determines which treatments to perform based on the patient's code. Only the physician performing the intervention will be aware of the code assigned to the patient. After evaluating the outcome, based on the patient's name, the collected information will be linked to the assigned code.

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

Ethical Committee of Isfahan University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, University Blvd., Arghwanieh, J Sharghi Street

City

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Province

Isfahan

Postal code

8155139998

Approval date

2023-02-21, 1401/12/02

Ethics committee reference number

IR.MUI.MED.REC.1401.407

Health conditions studied

1

Description of health condition studied

Colostomy

ICD-10 code

K94.00

ICD-10 code description

Colostomy complication, unspecified

Primary outcomes

1

Description

wound infection

Timepoint

One week, 1 month and 2 months after the operation

Method of measurement

doctor's examination

2

Description

Re-hospitalization

Timepoint

One week, 1 month and 2 months after the operation

Method of measurement

Asking the patient

Secondary outcomes

empty

Intervention groups

1

Description

In the first intervention group (traditional protocol), the patient remains fasting for 5 days after the operation,

and we prescribe albumin, vitamins and carbohydrates (dextrose serum) for the patient, and put him under intravenous nutrition, and the diet does not start earlier than 5 days.

Category

Treatment - Drugs

2**Description**

In the second intervention group (ERAS), usually 24 to 48 hours after the operation, depending on when the patient defecates, we start the liquid diet for the patient and do not put the patients under intravenous nutrition.

Category

Treatment - Other

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

Imam Hossein Hospital

Full name of responsible person

Dr. Mehrdad Hosseinpour

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km 10, Imam Khomeini Street

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

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mehrdad Hosseinpour

Position

Member of the university faculty

Latest degree

Subspecialist

Other areas of specialty/work

Pediatric surgery

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity
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Position
Member of the university faculty
Latest degree
Subspecialist
Other areas of specialty/work
Pediatric surgery
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Province

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available