Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

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

Public title
Evaluation of the results of using the ERAS protocol in the process of recovery of children in need ofcolostomy

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 sever 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
Isfahan

Province
Isfehan

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

Street address
km 10, Imam Khomeini Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
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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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Person responsible for updating data

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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