Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

Effects of Enhanced Recovery After Surgery (ERAS) Program Implementation on Hospital Stay Duration and Costs in Children underwent Colostomy Closure Surgery

Protocol summary

Study aim
Evaluation of the Enhanced Recovery After Surgery (ERAS) program implementation effects in patients undergoing colostomy closure surgery in pediatric surgery ward of Akbar Hospital

Design
Randomized controlled clinical trial on 160 patients randomized using opaque sealed envelopes method

Settings and conduct
In the initial visit by the paediatric surgeon at Akbar hospital, Mashhad, patients are randomly assigned, following the explanation and written informed consent. Postoperatively, during hospitalization, and after one month of discharge, data will be recorded by the relevant registrar and blindly delivered to the analyst.

Participants/Inclusion and exclusion criteria
Patients aged 28 days to 14 years who had a history of colostomy and are candidates for colostomy closure will enrol in the study. Patients with a history of underlying disease that leads to impaired tissue repair will not enrol.

Intervention groups
In the intervention group, the ERAS protocol is performed. This protocol briefly includes a set of measures before, during and after surgery to minimize fasting, bed rest time, and opioid use in patients. Patients will drink clear fluids up to two hours before surgery. Immediately after full consciousness, the fluid intake will begin as tolerated, and then the complete diet is started. In the control group, according to the routine of the surgical ward, patients will be NPO (nothing by mouth) 12 hours before surgery and receive intravenous antibiotics before surgery, and in some cases, mechanical preparation of the intestine with serial enema is applied. After surgery, patients will receive opioids in case of pain. Also, they would be NPO for up to 72 hours after surgery, followed by the regular diet, if the liquid diet is tolerated.

Main outcome variables
Duration of hospitalization; Time interval to tolerate oral intake

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191027045254N1**
Registration date: **2021-11-27, 1400/09/06**
Registration timing: **prospective**

Last update: **2021-11-27, 1400/09/06**
Update count: **0**

Registration date
2021-11-27, 1400/09/06

Registrant information
Name
Reza Ŝhojaeian
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3766 5574
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shojaeianr@mums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-01-10, 1400/10/20
Expected recruitment end date
2022-08-11, 1401/05/20
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of Enhanced Recovery After Surgery (ERAS) Program Implementation on Hospital Stay Duration and Costs in Children underwent Colostomy Closure Surgery

Public title
Effectiveness of Enhanced Recovery After Surgery (ERAS)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 28 days to 14 years History of a prior surgery resulted in a colostomy Being a candidate of colostomy closure surgery
Exclusion criteria:
Underlying disease that leads to tissue repair impairments (such as sever malnutrition or connective tissue disease
Age
From **28 days** old to **14 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
Using a table of random numbers, the researcher determines the direction to read the numbers and touches one of the numbers with his eyes closed. When each item enters the study, the researcher moves in a predetermined direction. Even numbers will be assigned to the intervention group and odd numbers to the control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, data analyst is blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Medical Faculty, Mashhad University of Medical Sciences
Street address
Faculty of Medicine, Mashhad University of Medical Sciences, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Approval date
2021-05-11, 1400/02/21
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1400.170

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
Duration of hospitalization: The total number of hospitalization days as the days between the date of discharge and date of hospitalization
Timepoint
Once after patients discharge
Method of measurement
Based on the date of admission and date of discharge, recorded in the hospital information system

2

Description
Time interval to tolerate oral intake: time interval between end of surgery and first oral feeding followed by no vomiting in hours
Timepoint
Once durnig hospital stay after oral intake tolerance
Method of measurement
Interval between the time of the first tolerated feeding recorded by the patient's nurse and the end time of the operation recorded in the operation report sheet in hours

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: ERAS protocol is performed in the patients of the intervention group. Implementation of the ERAS protocol includes the following: A. Preoperative: Intestinal prep only by oral Metronidazole, administration of clear liquids up to 2 hours before surgery, carbohydrate load as a serving of apple juice at two hours before surgery, Gabapentin loading dose of 15 mg/kg body weight three hours before surgery. B. Intraoperative: prophylactic antibiotic before surgical incision, prefer minimally invasive methods, not using unnecessary drains and tubes such as nasogastric tubes, maintaining normal temperature during surgery and preventing hypothermia, local anesthesia and regional blocks if effective, reduction and elimination of opioids, restriction of crystalloid intravenous fluids to 3-4 ml/kg/h. C. Postoperative: immediate limited mobility after surgery, limited clear fluid intake immediately after surgery as tolerated followed by normal diet, minimizing intravenous fluids and no bolus serum administration, avoiding opioids to relieve pain and administration of Acetaminophen 10 mg/ kg every 6 hours (maximum 650 mg every 6 hours), Ketorolac 0.5 mg/kg every 6 hours (maximum 30 mg every 6 hours), and Gabapentin 10 mg/kg every 8 hours (maximum 600 mg each 6 hours), control of nausea and vomiting by intravenous Ondansetron 0.1 mg/kg every 8 hours, aggressive and serious respiratory physiotherapy, and administration of intestinal motility drugs.

Category

Treatment - Other

2

Description

Control group: According to the routine of the surgical ward, patients will be NPO (nothing by mouth) 12 hours before surgery, receive intravenous antibiotics before surgery, and in some cases, mechanical preparation of the intestine with serial enema is applied. After surgery, patients will receive opioids in case of pain. Also, they would be NPO for up to 72 hours after surgery, followed by the normal diet, if the fluid diet is tolerated.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar children's hospital

Full name of responsible person

Reza Shojaeian

Street address

Akbar children's hospital, Shahid Kaveh Blvd.

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Mashhad

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

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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

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
Mashhad University of Medical Sciences
Full name of responsible person
Reza Ŝhojaeian
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatric surgery
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Reza Ŝhojaeian
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact
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Student
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General Practitioner
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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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable