

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 Shojaeian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3766 5574

Email address

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 during 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.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177897157

Phone

+98 51 3871 3801

Fax

+98 51 3870 9201

Email

alirezakhadembashi@gmail.com

Web page address

<http://akbar.mums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Daneshgah St., Qorashi building, Research and technology department

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Fax

+98 51 3843 0249

Email

vcresraech@mums.ac.ir

Web page address

<https://v-research.mums.ac.ir>

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 Shojaeian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatric surgery

Street address

3rd unit, No. 109, Farhad 15 St., Malekabad Blvd.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177897157

Phone

+98 51 3766 5574

Fax**Email**

shojaeianr@mums.ac.ir

shojaeianr@mums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Alireza Khadembashi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

No. 12, 17th Ebadi St., Ebadi Blvd.

City

Mashhad

Province

Razavi Khorasan

Postal code

9145736331

Phone

+98 51 3221 1307

Email

alirezakhadembashi@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Reza Shojaeian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatric surgery

Street address

3rd unit, No. 109, Farhad 15 St., Malekabad Blvd.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177897157

Phone

+98 51 3766 5574

Fax**Email****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