Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The impact of an innovative oral feeding approach on reducing ileus after elective open bowel surgeries: A comparison with traditional oral feeding

Protocol summary

Study aim

this study aims to evaluate the efficacy and safety of a newly designed early and gradual oral feeding protocol to determine whether it can lead to faster recovery of bowel function, shorter duration of postoperative ileus, and reduced length of hospital stay compared with traditional feeding practices.

Design

Single-center, randomized, parallel-group interventional clinical trial with equal allocation to intervention and control arms.

Settings and conduct

This interventional clinical trial was conducted in the Department of Surgery at Sina Hospital, Tehran University of Medical Sciences, on 113 adult patients undergoing elective open colorectal surgery. Patients were equally randomized (1:1) using computer-generated allocation (GraphPad Software) to either an innovative oral feeding protocol or conventional postoperative feeding, with data prospectively collected and analyzed using SPSS.

Participants/Inclusion and exclusion criteria

Adults (≥18 years) scheduled for elective open colorectal surgery, with ASA class I–III and no pre-existing gastrointestinal motility disorders, were included after providing written informed consent. Exclusions applied to those undergoing emergency surgery, with prior motility disorders, chronic opioid use, recent major abdominal surgery, intraoperative complications, or postoperative conditions preventing early oral feeding or protocol adherence.

Intervention groups

The intervention group received Clear fluids were given gradually—15 mL every 15, 10, and 5 minutes over successive 12- and 24-hour periods. Most patients tolerated a full fluid diet by 48 hours and began solid food at 72 hours.

Main outcome variables

Time to first passage of gas or stool/Return of bowel sounds/Time to initiation of first solid diet/Rate of nasogastric tube reinsertion /Incidence of postoperative complications/lenght of hospital stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220530055031N8**
Registration date: **2025-10-22, 1404/07/30**
Registration timing: **prospective**

Last update: **2025-10-22, 1404/07/30**
Update count: **0**

Registration date

2025-10-22, 1404/07/30

Registrant information

Name

Seyed Amir Miratashi Yazdi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-11-22, 1404/09/01

Expected recruitment end date

2027-02-20, 1405/12/01

Actual recruitment start date

2025-11-22, 1404/09/01

Actual recruitment end date

2027-02-20, 1405/12/01

Trial completion date

2027-04-21, 1406/02/01

Scientific title

The impact of an innovative oral feeding approach on reducing ileus after elective open bowel surgeries: A comparison with traditional oral feeding

Public title

Assessing a novel oral feeding strategy to prevent postoperative ileus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients aged 18 years or older., Patients scheduled for elective open colorectal surgery. Patients with no pre-existing gastrointestinal motility disorders. Patients with American Society of Anesthesiologists (ASA) physical status classification I–III. Patients able to provide written informed consent

Exclusion criteria:

Patients who underwent emergency colorectal surgery (e.g., for bowel obstruction, perforation, or peritonitis). Patients with a history of gastrointestinal motility disorders, such as gastroparesis, irritable bowel syndrome, or chronic constipation. Patients with chronic opioid use for more than two weeks prior to surgery. Patients who had major abdominal surgery within the previous six months. Patients who experienced intraoperative complications requiring deviation from the standard ERAS protocol. Patients requiring postoperative mechanical ventilation for more than 24 hours Patients who were unable to initiate oral feeding within 24 hours after surgery. Patients with cognitive impairments or language barriers that interfered with adherence to the feeding protocol.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **226**

More than 1 sample in each individual

Number of samples in each individual: **113**

Clinical data were collected for each participant, including demographic characteristics, surgical details, and postoperative outcomes.

Actual sample size reached: **226**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned to either the control or intervention group using stratified randomization based on age, gender, BMI, and presence of major comorbidities to ensure balanced distribution of these key variables across groups. how is it possible

Blinding (investigator's opinion)

Single blinded

Blinding description

This was a single-blinded study. While both the participants and the nurse responsible for the data collection were aware of group assignments, the data analyst remained blinded to group allocation throughout the analysis process.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committe of Tehran University of Medcial Science

Street address

Tehran University of Medical Sciences, 16th Azar St., Enghelab Sq., Tehran, Iran

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Postal code

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Approval date

2025-10-14, 1404/07/22

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1404.432

Health conditions studied

1

Description of health condition studied

Postoperative ileus (POI) is a temporary impairment of bowel motility that commonly occurs after abdominal or colorectal surgery. It delays the return of normal gastrointestinal function, leading to abdominal distension, nausea, vomiting, intolerance to oral intake, and prolonged hospitalization. The study investigates strategies to reduce the duration and severity of postoperative ileus in patients undergoing elective open colorectal surgery.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Resolution of postoperative ileus (POI) was defined as the return of bowel sounds and first passage of gas or stool in the absence of abdominal distension or vomiting. The need for nasogastric tube reinsertion (in cases of vomiting exceeding 100 mL within the first 24 hours) was recorded as an indicator of feeding intolerance and persistence of ileus.

Timepoint
Monitoring was performed continuously from recovery until discharge, with key assessment intervals corresponding to the oral feeding protocol at 0–12 hours, 12–24 hours, 24–48 hours, and 48–72 hours postoperatively (reflecting the initiation and progression of oral feeding). The time of first passage of gas or stool, return of bowel sounds, and initiation of the first solid diet were recorded daily until discharge.

Method of measurement
Bedside clinical examination: Assessment of bowel sounds and evaluation of abdominal distension.Recording of clinical events by the nurse or clinical team, including the time of first passage of gas or stool, tolerance of oral diet, and the volume of vomiting (for determining the need for nasogastric tube reinsertion).Data extraction from patient medical records and case report forms (CRFs), followed by statistical analysis using SPSS software.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the intervention group received standard perioperative, intraoperative, and postoperative care according to the ERAS protocol. However, postoperative oral feeding followed a structured regimen designed to stimulate early gut motility. Upon full recovery from anesthesia and stabilization of vital signs, oral intake was initiated as follows: • First 12 hours: 15 mL of clear fluid every 15 minutes• Next 12 hours: 15 mL every 10 minutes • Following 24 hours: 15 mL every 5 minutes By 48 hours postoperatively, most patients were able to tolerate a full fluid diet. Solid food was introduced at 72 hours post-surgery. In cases where vomiting exceeded 100 mL within the first 24 hours, a nasogastric tube was reinserted, and oral feeding was temporarily paused

Category
Treatment - Other

2

Description
Control group: Patients in the control group received the Standard ERAS protocol, including early initiation of oral feeding after anesthesia recovery. However, unlike the intervention group, there was no standardized feeding schedule. The volume and timing of oral intake were determined by clinical judgement, based on individual patient tolerance.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Hospital

Full name of responsible person
Seyed Amir Miratashi Yazdi

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Sina Hospital, Hasan Abad Square, Imam Khomeini Avenue, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Seyed Amir Miratashi Yazdi

Position

Assosciate Proffesor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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Name of organization / entity

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Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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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

Deidentified demographic data, surgical details, and postoperative outcome variables (e.g., duration of ileus, length of hospital stay).

When the data will become available and for how long

Within 6 months after publication and for up to 3 years

thereafter.

To whom data/document is available

Deidentified data and related documents will be available to qualified researchers affiliated with academic or research institutions, upon reasonable request, for purposes of independent verification, meta-analysis, or secondary scientific analyses, provided that data sharing complies with ethical and institutional regulations.

Under which criteria data/document could be used

The shared data and documents may be used only for research purposes that are scientifically valid, ethically approved, and consistent with the objectives of the original study. Researchers must provide a formal data-sharing request, including a brief proposal outlining the intended analyses, and obtain approval from the Ethics Committee of Tehran University of Medical Sciences before data access is granted.

From where data/document is obtainable

Researchers may request data by contacting the corresponding investigator via email at [amiratashi@sina.tums.ac.ir]. Requests will be reviewed for scientific validity and compliance with ethical guidelines.

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

Researchers may request data by contacting the corresponding investigator via email at [insert your email]. Requests will be reviewed for scientific validity and compliance with ethical guidelines.

Comments