Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effectiveness of loperamide and diphenoxylate in controlling the output of protective ileostomy in rectal cancer patients in Sinai Hospital in ۱۴۰۲-۱۴۰۳

Protocol summary

Study aim

Determining and comparing the efficacy of loperamide and diphenoxylate in controlling the output of protective ileostomy in rectal cancer patients

Design

It is a randomized clinical trial study with a control group in a single-blind manner on 122 patients in 2 groups.

Settings and conduct

Patients who had a protective ileostomy (loop) installed in Sinai Hospital due to rectal cancer from 1402 to 1403 were randomly divided into one of 2 groups: loperamide, loperamide and diphenoxylate. become

Participants/Inclusion and exclusion criteria

Determining and comparing the efficacy of loperamide and diphenoxylate in controlling the output of protective ileostomy in rectal cancer patients

Intervention groups

Patients will be randomly divided into 2 groups, and one group will receive loperamide. loperamide was started at 6 mg/day and increased daily by increments of 2-4 mg/day based on output and patient response, up to a maximum of 16 mg/day. In the Combination Group, loperamide (starting at 6 mg/day; maximum 16 mg/day) was administered alongside diphenoxylate, which was initiated at 5 mg/day and increased daily by 5 mg/day to a maximum of 20 mg/day

Main outcome variables

Ileostomy output ≤ 1500 g/day

General information

Reason for update

The primary reason for this update is that participant recruitment has now been completed. As the trial has concluded, we are updating the IRCT record to reflect the precise intervention details and study implementation. This includes correcting the description of intervention arms, adjusting the recruitment period to its actual duration, and updating the blinding status to accurately reflect the conducted trial. These updates are being made to ensure full transparency and alignment with the finalized protocol. The original sample size of 40 participants was determined based on initial feasibility estimates and limited preliminary data. However, as the study progressed, interim observations and variability in patient outcomes indicated that a larger sample would be necessary to ensure adequate statistical power to detect clinically meaningful differences between the two intervention groups. Additionally, patient recruitment was slower than anticipated due to periodic disruptions in surgical scheduling and variability in postoperative ileostomy output among referred patients. As a result, the recruitment period was extended to allow for the inclusion of a sufficient number of eligible participants, ultimately improving the robustness and generalizability of the study findings. The final sample size was increased to a total of n=120 patients, with an equal allocation ratio, while adhering strictly to the original inclusion and exclusion criteria and maintaining full protocol compliance throughout. Blinding status updated from single-blinded to open-label. Initially, the study was planned to be single-blinded, with the intention of blinding participants to group allocation. However, as the trial was being planned, it became evident that due to the difference in medication regimens — with one group receiving a single agent (loperamide) and the other receiving a combination of loperamide and diphenoxylate-atropine — maintaining blinding was not practically feasible. The number and type of medications taken differed between groups, and matched placebos were not available to conceal treatment allocation. Therefore, the study was conducted as an open-label trial to ensure practical implementation while maintaining methodological rigor.

Acronym

IRCT registration information

IRCT registration number: **IRCT20220530055031N4**
Registration date: **2023-10-21, 1402/07/29**
Registration timing: **prospective**

Last update: **2025-04-17, 1404/01/28**
Update count: **1**

Registration date
2023-10-21, 1402/07/29

Registrant information
Name
Seyed Amir Miratashi Yazdi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
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Email address
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-11-22, 1402/09/01
Expected recruitment end date
2025-02-19, 1403/12/01
Actual recruitment start date
2023-11-22, 1402/09/01
Actual recruitment end date
2025-02-19, 1403/12/01
Trial completion date
2025-03-10, 1403/12/20

Scientific title
Comparing the effectiveness of loperamide and diphenoxylate in controlling the output of protective ileostomy in rectal cancer patients in Sinai Hospital in ۱۴۰۲-۱۴۰۳

Public title
Comparing the effectiveness of Loperamide and Diphenoxylate in controlling the output of protective ileostomy in rectal cancer patients in Sinai Hospital in 1402-1403
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who underwent surgery due to rectal cancer and protective ileostomy were installed
Exclusion criteria:
Patients who have a history of taking drugs that affect the function and motility of the digestive system within 2 weeks before the study Age below 18 years
Age
From **18 years** old
Gender
Both

Phase
N/A

Groups that have been masked
No information
Sample size
Target sample size: **120**
Actual sample size reached: **122**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly divided into one of 2 groups: loperamide, loperamide and diphenoxylate. Block randomization with different block sizes is used to randomly assign two groups with 60 participants in each group (120 patients in total). The size of the blocks is a multiple of 2 and the divisor is 20. Initially, the block sizes are chosen randomly. Then, for each block, different permutations are determined for equal group size. Finally, one of the permutations is randomly selected and random numbers are generated using a computer in an independent statistical unit.
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
Ethics committee of medical faculty of Tehran University of Medical Sciences
Street address
Room 604, 6th floor, Tehran University of Medical Sciences Central Building, Keshavarz Blvd., Qods St. intersection
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2025-10-11, 1404/07/19
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.371

Health conditions studied

1

Description of health condition studied
Output of ileostomy
ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Ileostomy output
Timepoint
The second day to the sixth day after the operation every 24 hours
Method of measurement
The output of the ostoma is collected in plastic containers with appropriate labels provided by the department

Secondary outcomes

1

Description
Drug complication
Timepoint
Within 5 days of starting the drug
Method of measurement
Expert opinion

Intervention groups

1

Description
Intervention group: Intervention group: In this group, after ileostomy operation, they receive loperamide at a dose of 2 mg three times a day every 8 hours along with diphenoxylate at a dose of 2.5 mg twice a day every 12 hours. On the next day, if he does not respond to the treatment, loperamide at a dose of 2 mg four times a day every 6 hours along with diphenoxylate at a dose of 2.5 mg 4 times a day every 6 hours. Then loperamide at a dose of 4 mg three times a day every 8 hours along with diphenoxylate at a dose of 5 mg three times a day every 8 hours. Then loperamide at a dose of 4 mg four times a day every 6 hours along with diphenoxylate at a dose of 5 mg four times a day every 6 hours (maximum dose of loperamide 16 mg and maximum dose of diphenoxylate 20 mg). In this group of patients, loperamide and diphenoxylate are given to patients with maximum intervals (for example, twice a day with an interval of 12 hours, three times a day with an interval of 8 hours, and four times a day with an interval of 6 hours).
Category
Treatment - Drugs

2

Description
Control group: a group of patients who only receive routine treatment. Loperamide patients with a dose of 2 mg three times a day every 8 hours. On the next day, if he does not respond to the treatment, loperamide at a dose of 2 mg four times a day every 6 hours. Then loperamide at a dose of 4 mg three times a day every 8 hours. Then loperamide at a dose of 4 mg four times a day every 6 hours (maximum dose of loperamide 16 mg).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Seyed Amir Miratashi
Street address
Sina Hospital, Imam Khomeini Ave.
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1136746911
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hosp_sina@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi
Street address
Research and Technology Vice-Chancellor, 6th floor, Central Organization of the University, Keshavarz Blvd., corner of Quds St.
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vcr@sina.tums.ac.ir
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
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
No - There is not 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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The entire data will be shared after unidentifying people personal data
When the data will become available and for how long
6 months after publishing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used

In order to perform further research with the request from the scientific institute

From where data/document is obtainable

Dear applicants will be referred to Sina Hospital's scientific Center for access to Documents and Data or the applicant can email the project executor. the email address is available. (amiratashi@sina.tums.ac.ir)

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

After receiving the letter from the project executor, the applicant can refer to Sina Hospital Research Center and after the approval of the executor, the documents and data will be available to the executor within a week or the applicant can email directly to the project executor so the executor provide the information

Comments