

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of two bowel preparation regimens for colonoscopy: high-dose polyethylene glycol versus low-dose polyethylene glycol combined with senna

Protocol summary

Study aim

Comparison between two bowel preparation regimens for colonoscopy: high-dose polyethylene glycol (PEG) and low-dose polyethylene glycol combined with senna

Design

A Controlled clinical trial with parallel groups, single-blind, randomized with permuted blocks on 362 patients.

Settings and conduct

Patients referred to the Taleghani Hospital Gastroenterology Clinic, who have inclusion criteria and no exclusion criteria will be placed in one of two control or intervention groups and will undergo colonoscopy by two endoscopists unaware of the patient's diet.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: More than 18 year-olds, written consent, Indications for colorectal cancer screening, positive fecal occult blood, iron deficiency anemia in men or postmenopausal women, Lower gastrointestinal symptoms, involuntary weight loss, Abnormal abdominal imaging. Exclusion Criteria: Hypersensitivity to PEG or senna, Taking laxatives within one week before colonoscopy, Previous colonic surgery, Known or suspected bowel obstruction, Prior history of colonoscopy.

Intervention groups

Intervention group: Half of the agents will be administrated at 4 pm the day before and the second half in the morning of the colonoscopy up to 5 hr before the procedure. 3 sachets of polyethylene glycol powder (210 g) (Sepidaj Pharmaceutical Company) with senna solution (120 ml) (Iran Darok Company) will be administrated in two divided doses. Control group: at the same time, 6 sachets of polyethylene glycol powder (420 g) will be administrated in divided doses.

Main outcome variables

Bowel preparation scale (Boston Bowel Preparation Scale), adverse effects of colon cleansers agents

(nausea, vomiting, abdominal pain, bloating, headache, vertigo, sleeplessness)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211101052935N1**

Registration date: **2022-05-13, 1401/02/23**

Registration timing: **retrospective**

Last update: **2022-05-13, 1401/02/23**

Update count: **0**

Registration date

2022-05-13, 1401/02/23

Registrant information

Name

Mohsen Rajabnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2303 1799

Email address

dr.rajabnia@outlook.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-28, 1399/12/10

Expected recruitment end date

2022-03-01, 1400/12/10

Actual recruitment start date

2021-02-28, 1399/12/10

Actual recruitment end date

2021-11-01, 1400/08/10

Trial completion date
2021-11-01, 1400/08/10

Scientific title
Comparison of two bowel preparation regimens for colonoscopy: high-dose polyethylene glycol versus low-dose polyethylene glycol combined with senna

Public title
Investigating the effect of senna on preparation for colonoscopy

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
People more than 18 year-old. Giving a written consent. Indications for colorectal cancer screening, include: average-risk screening, increased-risk screening (patients with one or more first degree relative[s] with colorectal cancer [CRC] or colorectal adenomas, hereditary CRC syndromes), positive fecal occult blood test, documented iron deficiency anemia in men or postmenopausal women. Lower gastrointestinal symptoms such as unexplained chronic clinically significant diarrhea, or unexplained involuntary weight loss. Abnormal abdominal imaging such as abnormalities detected on barium enema, abdominal computed tomography and etc.
Exclusion criteria:
Hypersensitivity to polyethylene glycol or senna Taking laxatives within one week prior to colonoscopy Previous colonic resection surgery Known or suspected bowel obstruction Prior history of colonoscopy

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
• Outcome assessor

Sample size
Target sample size: **362**
Actual sample size reached: **402**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on sample size of study, 100 blocks with a size of 4 (such as AABB, ABAB, etc.) in a randomly varied order, will be used for random allocation. Random blocks will be provided by GraphPad software. The blocks will be placed one after the other in sequence, from the first to the 100th of them (equivalent to the first to the 400th patient). For example, if the blocks that will be provided by the software are AABB, BBAA, ABAB, respectively, the order of patients' bowel preparation regimens will be AABBABBBBAA. The order of the blocks (100 provided blocks, it means arranging 400 bowel preparation regimens for 400 patients) will be reposed to the clinic secretary. Patients who will be candidates for

colonoscopy, do not meet the exclusion criteria, and declare their informed consent to enter the study, will receive a preparation regimen based on the provided blocks A or B, respectively.

Blinding (investigator's opinion)
Single blinded

Blinding description
The endoscopist does not know which class of medications had been used by the patient for preparation. Therefore, he/she reports the patient's preparation in the colonoscopy report, regardless of the preparation regimen.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
Gastroenterology and Liver Diseases Research Institute, Shahid Beheshti University of Medical Science
Street address
Gastroenterology and Liver Diseases Research Institute, No 1, Ayatollah Taleghani Hospital, Shahid Arabi Ave., Yaman St., Shahid Chamran Highway, Tehran.
City
Tehran
Province
Tehran
Postal code
1985711151
Approval date
2021-02-24, 1399/12/06
Ethics committee reference number
IR.SBMU.RIGLD.REC.1399.064

Health conditions studied

1
Description of health condition studied
colonoscopy preparation
ICD-10 code
ICD-10 code description

Primary outcomes

1
Description
Quality of colon preparation
Timepoint

During colonoscopy (within first 24 hours after use regimens)
Method of measurement
Endoscopist report based on BBPS (Boston Bowel Preparation Scale)

Secondary outcomes

1

Description

Adverse effects of preparation regimens

Timepoint

While taking the drug until colonoscopy

Method of measurement

patients report

Intervention groups

1

Description

Control group: In this study, all patients will undergo colonoscopy in the afternoon and we will use a split-dose preparation, i.e., administering half of the colon cleansing agent in the evening (4 pm) before colonoscopy and the remaining in the morning (Five hours before the procedure). Patients in the control group will receive 6 sachets of polyethylene glycol powder (420 g) (Sepidaj Pharmaceutical Company), at 4 pm on the prior day of colonoscopy to 5 hours before the procedure.

Category

Other

2

Description

Intervention group: In this study, all patients will undergo colonoscopy in the afternoon and we will use a split-dose preparation, i.e., administering half of the colon cleansing agent in the evening (4 pm) before colonoscopy and the remaining in the morning (Five hours before the procedure). Patients in the intervention group will receive 3 sachets of polyethylene glycol powder (210 g) (Sepidaj Pharmaceutical Company), along with senna solution (120 ml) (Iran Darok Company) in two divided doses of 60 ml. The first dose will be given at 4 pm on the prior day of the colonoscopy and the second dose on the morning of the procedure (five hours before the procedure).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital-Tehran

Full name of responsible person

Mohsen Rajabnia

Street address

Gastroenterology and Liver Diseases Research Institute, No 1, Ayatollah Taleghani Hospital, Shahid Arabi Ave., Yaman St., Shahid Chamran Highway, Tehran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammadreza Zali

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Gastroenterology and Liver Diseases Research Institute, No 1, Ayatollah Taleghani Hospital, Shahid Arabi Ave., Yaman St., Shahid Chamran Highway, Tehran.

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

50

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

Sponsor**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Vice-chancellor in research affairs, No 1, Shahid Beheshti university of medical sciences, Shahid Arabi Ave., Yaman St., Shahid Chamran Highway, Tehran.

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

50

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohsen Rajabnia

Position

Adult gastroenterology and hepatology subspecialist assistant

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amir Sadeghi

Position

associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohsen Rajabnia

Position

Gastroenterology and hepatology subspecialist assistant

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

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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

No further information available.

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