

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of adding erythromycin and metoclopramide to the standard diet of colonoscopy in colonoscopy preparation

Protocol summary

Study aim

Effective method of intestinal preparation in patients undergoing colonoscopy referred to Shahid Beheshti Hospital in Qom

Design

A clinical trial study include control group and four intervention groups (70 participant in each group) is selected by the available sampling method. By analyzing the use of opaque envelopes sealed with random sequence (SNOSE) will be performed by the analyzer itself.

Settings and conduct

Peg powder at the time of consumption than from 10 am the day before colonoscopy at intervals of one hour so that the last glass at 1 o'clock in the morning of the colonoscopy (in 3 divided doses with an interval of 8 hours Peg), the second tablet at 5 pm the day before Patients will be given a colonoscopy and a third pill at 1 a.m. on the day of the colonoscopy. Colonoscopy will be performed between 9 am and 1 pm by a gastroenterologist (to standardize the examination method) using a colonoscope for 15 to 30 minutes with the administration of painkillers and sedatives and local anesthesia by an anesthesiologist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18 years and older; Outpatients. Exclusion criteria: inflammatory bowel disease; intestinal obstruction; perforation; lung, heart disease; severe nausea; Patients with loss of consciousness and swallowing disorders; Patients with ileostomy; Patients with a history of drug allergy

Intervention groups

High volume pack - 4 liters; High volume pack + 3 tablets of metoclopramide 10mg; High volume pack + 3 tablets of metoclopramide 400mg + erythromycin 3 tablets of 400 mg; High volume pack + 3 tablets of metoclopramide 10mg + erythromycin 3 tablets of 400 mg; Low volume pack + 3 tablets of metoclopramide 10mg + erythromycin 3 tablets of 400 mg

Main outcome variables

Determining colon preparation quality: cecum intubation mean time; polyp detection frequency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210719051943N1**

Registration date: **2022-01-22, 1400/11/02**

Registration timing: **prospective**

Last update: **2022-01-22, 1400/11/02**

Update count: **0**

Registration date

2022-01-22, 1400/11/02

Registrant information

Name

mehdi pezeshki modares

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3612 2000

Email address

mpezeshkim@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of adding erythromycin and metoclopramide to the standard diet of colonoscopy in colonoscopy preparation

Public title
adding erythromycin and metoclopramide to the diet of colonoscopy preparation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18 years and older Outpatients
Exclusion criteria:
Intestinal inflammation Cardiopulmonary diseases severe nausea patients with decreased consciousness Patients with a history of drug allergy Intestinal perforation Intestinal obstruction

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **350**

Randomization (investigator's opinion)
Randomized

Randomization description
A stochastic sequence will be generated by the block analytics method using a limited block randomization method. Random allocation encryption will be performed by the analyzer itself using the method of using opaque sealed envelopes sealed with random sequence (SNOSE). Participants will attend the study over time and on a random. interventionism and control groups will be assigned based on accident (coin toss).

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 qom University of Medical Sciences

Street address
Beheshti Blv

City
Qom

Province
Ghous

Postal code
3719964797

Approval date
2021-05-02, 1400/02/12

Ethics committee reference number
IR. MUQ .REC.1400.017

Health conditions studied

1

Description of health condition studied

Colonoscopic preparation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Determining colon preparation quality

Timepoint

All colonoscopies will be performed in the period from 9 am to 1 pm by a gastroenterologist (to standardize the examination method). This may take between 15 and 30 minutes per person. clinical outcome assessed with colonoscopist during the procedure

Method of measurement

questionnaire

2

Description

cecum intubation mean time

Timepoint

All colonoscopies will be performed in the period from 9 am to 1 pm by a gastroenterologist (to standardize the examination method). This may take between 15 and 30 minutes per person. clinical outcome assessed with colonoscopist during the procedure

Method of measurement

questionnaire

3

Description

polyp detection frequency

Timepoint

All colonoscopies will be performed in the period from 9 am to 1 pm by a gastroenterologist (to standardize the examination method). This may take between 15 and 30 minutes per person. clinical outcome assessed with colonoscopist during the procedure

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: High volume peg 4 liters

Category

Treatment - Drugs

2

Description

Intervention group1: Peg high volume + 3 tablets 10 mg metoclopramide

Category

Treatment - Drugs

3

Description

Intervention group 2: Peg high volume +3 mg tablets 400 erythromycin+ 3 tablets 10 mg metoclopramide

Category

Treatment - Drugs

4

Description

Intervention group3: Peg high volume +3 tablets 20 metoclopramide + 3 erythromycin 400 mg tablets

Category

Treatment - Drugs

5

Description

Intervention group 4: Peg low volume + 2 mg 20 metoclopramide tablets

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Beheshti Hospital

Full name of responsible person

Mahdi Pezeshki Modares

Street address

Blv Beheshti

City

Qom

Province

Ghous

Postal code

3719964797

Phone

+98 25 3612 2526

Email

mpezeshkim@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ghous University of Medical Sciences

Full name of responsible person

Ehsan Sharifipour

Street address

Safashar

City

Qom

Province

Ghous

Postal code

3719964797

Phone

+98 25 3285 4011

Email

Ehsansharifipour@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ghous 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**

Ghous University of Medical Sciences

Full name of responsible person

Mehdi Pezeshki modares

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Beheshti BLV

City
Qom
Province
Ghoum
Postal code
3719964797
Phone
+98 25 3612 2000
Fax
Email
mpezeshkim@muq.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Mehdi Pezeshki modares
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Beheshti BLV
City
Qom
Province
Ghoum
Postal code
3719964797
Phone
+98 25 3612 2000
Fax
Email
mpezeshkim@muq.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Mahdi Pezeshki Modares
Position
Assistant professor
Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine
Street address
Blv. Beheshti
City
Qom
Province
Ghoum
Postal code
3719964797
Phone
+98 25 3612 2526
Email
mpezeshkim@gmail.com

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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All potential data can be shared after people have not been identified

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

It will be available for researchers working in academic and scientific institutions

Under which criteria data/document could be used

According to the rules of the COPE

From where data/document is obtainable

mpezeshkim@gmail.com

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

mpezeshkim@gmail.com

Comments