

# 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**

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**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

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Beheshti BLV

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## 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  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Position**  
Assistant professor  
**Latest degree**  
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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

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