

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### Randomized double blind clinical trial to compare the effect of polyethylene glycol and C-lax in bowel preparation for colonoscopy

#### Protocol summary

##### Summary

(1) Objectives: Comparing the effect of PEG and C-Lax in bowel preparation (2) Design: In this single center randomized double blind clinical trial, 300 eligible cases will randomly allocated to either of the 2 groups by endoscopy technician (3) Setting and conduct: In this study, among all patients candidate for colonoscopy exam in our academic hospital, 300 eligible cases will randomly allocated in either PEG or C-lax group to compare the effect of these two agents in bowel preparation by Ottawa score (4) Participants: All patients refereed for colonoscopy without heart failure, non-pregnant, no history of colectomy, older than 18 years-old (5) Intervention: Administration of PEG and C-Lax (6) Main outcome measures: Ottawa score (score and quality of bowel preparation)

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201601161264N7**  
Registration date: **2016-02-04, 1394/11/15**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-02-04, 1394/11/15

##### Registrant information

###### Name

Sima Besharat

###### Name of organization / entity

Golestan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 17 1224 4170

###### Email address

besharat@goums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Golestan University of Medical Sciences

###### Expected recruitment start date

2014-03-21, 1393/01/01

###### Expected recruitment end date

2016-03-19, 1394/12/29

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Randomized double blind clinical trial to compare the effect of polyethylene glycol and C-lax in bowel preparation for colonoscopy

###### Public title

Comparing the effect of polyethylene glycol and C-lax in bowel preparation for colonoscopy

###### Purpose

Diagnostic

###### Inclusion/Exclusion criteria

Exclusion criteria: Age less than 18 years; history of colectomy; any contraindication for colonoscopy (compromised congestive heart disease (class III and IV of American Heart Association); severe mental disease; pregnancy and lactation; patients' not willing to participate

###### Age

From **18 years** old to **80 years** old

###### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 300

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Golestan University of Medical Sciences

##### Street address

Research deputy, Falsafi educational complex,  
Shastkola road

##### City

Gorgan

##### Postal code

##### Approval date

2014-08-20, 1393/05/29

##### Ethics committee reference number

32189210226

## Health conditions studied

### 1

#### Description of health condition studied

Bowel functional disorders

#### ICD-10 code

K92.8

#### ICD-10 code description

Other specified diseases of digestive system

## Primary outcomes

### 1

#### Description

The quality of bowel preparation

#### Timepoint

At the time of colonoscopy

#### Method of measurement

Ottawa score

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Sachets of PEG powder rinsed in water (each sachet contains 70 grams of PEG rinsed in 4 glasses of water) , and patients will be asked to drink 250 mL of the solution every 15 minutes starting 24 hours before the procedure.

#### Category

Diagnosis

### 2

#### Description

In C-lax group, 3 bottles of C-lax syrup (each 60 mL bottle contains 90 mg Senozoids) in two split dose beginning from 24 before the procedure (1.5 bottles at 9 am and 1.5 bottles at 5 pm the day before colonoscopy).

#### Category

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sayyad-e-Shirazi Hospital

##### Full name of responsible person

##### Street address

##### City

Gorgan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Golestan University of Medical Sciences

##### Full name of responsible person

Hossein Taziki

##### Street address

Falsafi educational complex, Shastkola road

##### City

Gorgan

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Golestan University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

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

Golestan University of Medical Sciences

**Full name of responsible person**

Alireza Norouzi

**Position**

MD, Gastroenterologist

**Other areas of specialty/work****Street address**

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Alireza Norouzi

**Position**

MD

**Other areas of specialty/work****Street address**

GI department, Sayyad-e-Shirazi Hospital

**City**

Gorgan

**Postal code****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*