

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

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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

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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