Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the quality and quantity of colon preparation for colonoscopy with split doses and single-dose of PEG

Protocol summary

Study aim
Comparison of the quality of colon preparation for colonoscopy with split doses and single-dose of polyethylene glycol
Design
Clinical trial has two groups , parallel, blind, and randomized groups with 400 patient
Settings and conduct
Of the patients referring to the Sayyad Shirazi Educational Center in Gorgan, who are candidates for colonoscopy, 200 people are randomly assigned to receive the entire dose of PEG (4 liters) needed to clear the colon in previous night Of the colonoscopy (single dose group) and 200 individuals in the group receiving two-dose doses before colonoscopy at night and in morning before the colonoscopy.
Participants/Inclusion and exclusion criteria
Exclusion criteria: Less than 18 years old, history of colon resection , colonoscopy contraindications, severe mental illness, pregnancy and lactation, neurological diseases such as Parkinson's disease and stroke, patients' dissatisfaction.
Intervention groups
Intervention group 1: 200 people, receiving all of the polyethylene Glycol needed to clear the colon that was four liters during the night before colonoscopy.
Intervention group 2: Includes 200 people who receive two dose polyethylene glycol divided on night and the morning before colonoscopy.
Main outcome variables
Quality of colon preparation for colonoscopy

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180103038196N6**
Registration date: **2018-09-17, 1397/06/26**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-17, 1397/06/26**
Update count: **0**
Registration date
2018-09-17, 1397/06/26

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-08-23, 1397/06/01
Expected recruitment end date
2018-10-22, 1397/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the quality and quantity of colon preparation for colonoscopy with split doses and single-dose of PEG

Public title
The effect of split doses and single-dose of PEG in colon preparation
Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients are candidates for colonoscopy Age over 18 years old

Exclusion criteria:

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **400**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized method: Patients will be randomly selected using statistical software Randomization tool: Statistical software

Blinding (investigator's opinion)

Double blinded

Blinding description

In this way, a gastroenterologist who performs colonoscopy and Clinical care who training to use PEG has no information on the type of drug used for each patient.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

Street address

Golestan university of medical science ,Beginin of Shastkola Street, 5th Kilometers of Gorgan Sari Road, Gorgan

City

Gorgan

Province

Golestan

Postal code

4918936316

Approval date

2017-10-23, 1396/08/01

Ethics committee reference number

ir.mazums.rec. 1397.1249

Health conditions studied

1

Description of health condition studied

Quality of colon preparation for colonoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Colon preparation for colonoscopy using Ottawa scoring system

Timepoint

At Colonoscopy time

Method of measurement

Colon preparation for colonoscopy using Ottawa scoring system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The group will used Polyethylene glycol in a single dose at night before colonoscopy.

Category

Treatment - Other

2

Description

Intervention group 2: In this group, patients receive a two-liter dose in divided doses during the night before and on the morning of the colonoscopy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayyad Shirazi Hospital in Gorgan

Full name of responsible person

Dr Mozaffar Emami

Street address

Sayyad Shirazi Hospital , Sayyad Shirazi Blv, Gorgan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gorgan University of Medical Sciences

Full name of responsible person
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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
Gorgan 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
Gorgan University of Medical Sciences

Full name of responsible person
Dr Mozaffar Emami

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

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Person responsible for updating data

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Dr Amir Hossein Salimi

Position
General practitioner

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Data are obtainable after individuals were unidentified
When the data will become available and for how long
Start the access after 6 months after establishing the results
To whom data/document is available
Professors and medical students
Under which criteria data/document could be used
nothing
From where data/document is obtainable
Send email to salimia92@gmail.com
What processes are involved for a request to access data/document
Using email
Comments
nothing