

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Sep 2026

Compararson of two different methods of colon cleansing for colonoscopy (colonoscopy morning than the evening before colonoscopy)

Protocol summary

Summary

There may be some good advantages if the prep and procedure become as 1-day process. In this study we hypothesized that AM-only dosing for afternoon colonoscopy is as effective as PM- dosing for achieving adequate cleansing and detecting colon lesions and furthermore that this administration schedule improves quality of life and sleep by interfering less with the day before colonoscopy. 18-80 years at age outpatients to undergo elective afternoon (12 pm or later) colonoscopy at a university hospital based on inclusion and exclusion criteria were eligible to participate . Exclusion criteria included pregnancy-breast feeding->50% colon resection-sever constipation-known or suspected gastroparesis-sever nausea or vomiting-bowel obstruction-heart failure-renal failure. Using randomization eligible patients were assigned to AM or PM PEG by an investigator not involved in the colonoscopy procedure. The endoscopist was not involved in the randomization process. All study procedures were performed by an attending physicion . Subjects randomized to PM dose PEG were instructed to take 4 liters of water plus 4 pack PEG powder from 6 PM the afternoon before colonoscopy (250 ml every 15 min) Subjects assigned to AM took 4 liter of water plus 4 pack PEG powder 6 am day of colonoscopy . Patients completed a questionnaires evaluating tolerance /sleep/ working quality and side effect of PEG. Tolerance and work quality was measured using a 10- point Likert scale and side effect in patients was evaluated .sleep quality was measured by comparing the averarage number of hours the patient normally sleeps to the number of hours they slept the night before colonoscopy. Primary trial end point was the prep quality .other end points included side effects measures of quality of life sleep quality flush need and colonoscopy findings. During the procedure the endoscopist recorded total procedure and time of procedure finding and quality of preparation for the whole colon and amount of flushing required.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107217080N1**

Registration date: **2013-08-29, 1392/06/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-29, 1392/06/07

Registrant information

Name

Javad Shokri Shirvani

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1223 8284

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Babol University of Medical Sciences

Expected recruitment start date

2013-04-22, 1392/02/02

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compararson of two different methods of colon cleansing for colonoscopy (colonoscopy morning than the evening before colonoscopy)

Public title

PEG effect on colon cleansing

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criterion:18-80 years old out patients Exclusion criteria: pregnancy; breast feeding; more than50% colon resection; sever constipation; known or suspected gastroparesis; sever nausea or vomiting; bowel obstruction; heart failure and renal failure.

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: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic comittee Babol university of medical science

Street address

Rohani hospital, Keshavarz Blvd, University Sq

City

Babol

Postal code

4717641367

Approval date

2013-04-21, 1392/02/01

Ethics committee reference number

2306

Health conditions studied

1

Description of health condition studied

Colonoscopy preparation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Quality of bowel cleansing

Timepoint

During colonoscopy

Method of measurement

Observation during colonoscopy

Secondary outcomes

1

Description

Side effect of PEG

Timepoint

Before and after colonoscopy

Method of measurement

Observation during colonoscopy-questionnaire

2

Description

Measures of quality of life

Timepoint

Before and after colonoscopy

Method of measurement

Observation during colonoscopy-questionnaire

3

Description

Sleep quality

Timepoint

Before and after colonoscopy

Method of measurement

Observation during colonoscopy-questionnaire

4

Description

Colonoscopy finding

Timepoint

Before and after colonoscopy

Method of measurement

Observation during colonoscopy-questionnaire

5

Description

Time of colonoscopy

Timepoint

Before and after colonoscopy

Method of measurement

Observation during colonoscopy-questionnaire

Intervention groups

1

Description

Subjects assigned to AM took 4 liter of water plus 4 pack PEG powder 6 am day of colonoscopy

Category

Diagnosis

2

Description

Subjects randomized to PM dose PEG were instructed to take 4 liters of water plus 4 pack PEG powder from 6 PM the afternoon before colonoscopy (250 ml every 15 min) that the standard schedule for colon cleansing.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Rouhani hospital and Beheshti hospital

Full name of responsible person

Javad Shokri MD

Street address

Rouhani hospital, Danesgah Square, Ganjafrooz Avenue, Babol

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice- chancellor of Researcher Babol University of Medical Sciences

Full name of responsible person

Dr Amrolah Mostafazadeh

Street address

Vice- chancellor of Researcher, Ganjafrooz Avenue, Daneshgah Square, Babol

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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

Vice- chancellor of Researcher Babol 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

Babol University of Medical Sciences

Full name of responsible person

Hassan Taheri MD

Position

Assistant professor

Other areas of specialty/work

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Medical resident

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Web page address**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