Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Compararsion 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

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Name of organization / entity
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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
Compararsion 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 haspital, Danesgah Square, Ganjafrooz Avenue, Babol
City
Babol

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
City
Babol
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
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Person responsible for updating data

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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