Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the effect of mechanical intestinal preparation with 6 and 4 packaged Polyethylene glycol with telephon based re-education before colonoscopy on adequacy of intestinal preparation, safety and acceptance of patients undergoing colonoscopy.

Protocol summary

Study aim
Comparison mechanical intestinal preparation with 6 and 4 packaged Polyethyleneglycol with telephon based re-education on adequacy of intestinal preparation, safety and acceptance of patients undergoing colonoscopy

Design
The intervention consists of 3 different groups as follows: the first group 4 packed polyethylene glycol , the second group 6 packed polyethylene glycol and the third group 4 packed polyethylene glycol with telephone base re-education. The groups were selected randomly using spss statistical software.

Settings and conduct
The site of sampling is the endoscopy department of Ghaem Hospital

Participants/Inclusion and exclusion criteria
1.To be satisfied to participate in the study. 2.Aged 18 to 64 years old. 3.At the present time, Not to be treated for liver and kidney disease. 4.There are no symptoms of intestinal obstruction (prolonged constipation, abdominal distension and sometimes sensitivity to touch, abdominal pain, nausea and vomiting, certain radiographic findings). 5.Has not History of surgery to remove all or part of the colon 6.Not be Pregnant 7.Not have hearing problem. Exclusion criteria 1.The Intestinal preparation protocol Completely dose not implementation. 2.Do not want to continue to cooperate

Intervention groups
The first group was 4 packed polyethylene glycols, the second group 6 packed polyethylene glycol and the third group 4 packed polyethylene glycol with telephone based re-education on before colonoscopy day.

Main outcome variables
The main consequences include adequacy of intestinal preparation, safety and patient acceptance under colonoscopy

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20171120037552N2**
Registration date: **2018-11-13, 1397/08/22**
Registration timing: **retrospective**

Last update: **2018-11-13, 1397/08/22**
Update count: **0**

Registration date
2018-11-13, 1397/08/22

Registrant information
Name
سیده نسرین ماشاالله
Name of organization / entity
دانشکده پرستاری و مامایی دانشگاه علوم پزشکی مشهد
Country
Iran (Islamic Republic of)
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mashallahn931@mums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-03-21, 1397/01/01
Expected recruitment end date
2018-08-21, 1397/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of mechanical intestinal preparation with 6 and 4 packaged Polyethylene glycol with telephon based re-education before colonoscopy on adequacy of intestinal preparation, safety and acceptance of patients undergoing colonoscopy.

Public title
Comparison of the effect of mechanical intestinal preparation with Polyethylene glycol

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
To be satisfied to participate in the study . Aged 18 to 64 years old. At the present time, Not to be treated for liver and kidney disease. There are no symptoms of intestinal obstruction (prolonged constipation, abdominal distension and sometimes sensitivity to touch, abdominal pain, nausea and vomiting, certain radiographic findings). Has not History of surgery to remove all or part of the colon. Not be Pregnant. Not have hearing problem.

Exclusion criteria:
The Intestinal preparation protocol Completely dose not implementate. Do not want to continue to cooperation.

Age
From **18 years** old to **64 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization tool using statistical software

Blinding (investigator's opinion)
Double blinded

Blinding description
1-Patients in the study are not known About the type of preparation regimen. 2-Routine Complications Preparation is measured through a Special research tool By researcher help that does not know of the preparation regimen. 3-The endoscopic specialist does not know the type of bowel preparation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee Mashhad University of medical sciences

Street address
Gaem hospital

City
Mashhad

Province
Razavi Khorasan

Postal code
91766-99199

Approval date
2018-02-17, 1396/11/28

Ethics committee reference number
IR.MUMS.REC.1396.380

Health conditions studied

1

Description of health condition studied
Patients under colonoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Adequacy of intestinal preparation, safety and patient acceptance under colonoscopy

Timepoint
Day of recurrences for colonoscopy and the day of colonoscopy

Method of measurement
The adequacy of intestinal preparation through the Boston instrument and the patient's acceptance through a checklist questionnaire and the safety of the patient are measured by checking blood electrolytes.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Four polyethylene glycol packages. Interventions include: On the first day, patients will eat soft diet and much fluid at least 24 to 30 glasses . The

second day, patients will eat' Smooth fluid and much fluid at least 24 to 30 glasses a day. Patients on the day of referral receive 4 packets of polyethylene glycol, 6 bisacodyl tablet and one bisacodyl suppository per day for colonoscopy. Patients take 2 packs of this powder plus 4 tablet of bisacodyl on the day before colonoscopy, and 2 packs of polyethylene glycol, 2 tablet of biacodyl and one bisacodyl suppository are taken on the morning of the colonoscopy. Also on the referral and colonoscopy day Blood tests are taken from patients. These tests include Mg, P, Na, k, Ca, BUN.cr.

Category

Diagnosis

2

Description

Intervention group 1: Six packet of polyethylene glycol. Interventions include: On the first day, patients will eat soft diet and much fluid at least 24 to 30 glasses . The second day, patients will eat' Smooth fluid and much fluid at least 24 to 30 glasses a day. Patients on the day of referral receive 6 packets of polyethylene glycol, 10 bisacodyl tablet and one bisacodyl suppository per day for colonoscopy. Patients take 4 packs of this powder plus 8 tablet of bisacodyl on the day before colonoscopy, and 2 packs of polyethylene glycol, 2 tablet of biacodyl and one bisacodyl suppository are taken on the morning of the colonoscopy. Also on the referral and colonoscopy day Blood tests are taken from patients. These tests include Mg, P, Na, k, Ca, BUN.cr.

Category

Diagnosis

3

Description

Intervention group 2: Four polyethylene glycol packets by telephone base re-education. Interventions include: On the first day, patients will eat soft diet and much fluid at least 24 to 30 glasses . The second day, patients will eat' Smooth fluid and much fluid at least 24 to 30 glasses a day. Patients on the day of referral receive 4 packets of polyethylene glycol, 6 bisacodyl tablet and one bisacodyl suppository per day for colonoscopy. Patients take 2 packs of this powder plus 4 tablet of bisacodyl on the day before colonoscopy, and 2 packs of polyethylene glycol, 2 tablet of biacodyl and one bisacodyl suppository are taken on the morning of the colonoscopy.In addition, the nurse on the day before the colonoscopy (second day), followed by a 5 to 10 minute phone call follow up by the patients in the third group and responded if there was a question. Also on the referral and colonoscopy day Blood tests are taken from patients. These tests include Mg, P, Na, k, Ca, BUN.cr.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
Endoscopy Center of Ghaem Hospital

Full name of responsible person
Dr mostafa dastani

Street address
Shariati Square Beginning of Boulevard Ahmad Abad

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Mashhad

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Razavi Khorasan

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Email
Quaem.Medical.Center@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr Mohsen Tafaghodi

Street address
Mashhad,beside Hoveize cinema.

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Vcresearch@mums.ac.ir

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Seyed Reza Mazlom

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Faculty of Nursing and Midwifery, Avicenna St., Avicenna Street, Mashhad, Iran.

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Seyed Reza Mazlom

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Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Seyede Nasrin Mashallah

Position
Master student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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mashallahn931@mums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The file contains patient information in the colonoscopy section.

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Part of the information that relates to the outcomes Unidentifiable will be shared.

When the data will become available and for how long
Start the access period 6 months after the results are published

To whom data/document is available
People working in scientific and academic and industry

Under which criteria data/document could be used
Doing an analysis on study data is not allowed

From where data/document is obtainable
seyede nasrin mashallah

What processes are involved for a request to access

data/document

If available and authorized to provide requested items as soon as possible

Comments