

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the three one day colon preparation methods with oral PEG, oral PEG plus bisacodyl suppository and oral PEG plus saline enema for colonoscopy in children

Protocol summary

Summary

Aim: In this study three methods for bowel preparation will be compared. Preparation score will be assessed according to validated Boston Bowel Preparation Score. **Inclusion criteria:** All children aged 2-21 years old who have indication for colonoscopy **Exclusion criteria:** Parental disagreement; History of previous gastrointestinal surgery; History of previous bowel preparation in 2 weeks; Uncooperative patients **Sample size:** Thirty cases in each group will be studied. **Intervention:** Group 1: For children weighed equal or greater than 45kg, 280 gram of polyethylene glycol per 2 liter mineral water will be administered orally. For children weighed < 45 kg, 140 gram of PEG per 1 liter of mineral water will be administered orally. Group 2: In addition to PEG as mentioned above, 5 mg bisacodyl suppository will be used three times at q8hr before colonoscopy. Group 3: In addition to PEG, 500 cc normal saline enema will be used two times at 12 hr interval before colonoscopy. Bowel preparation will be evaluated according to Boston Bowel Preparation Scale. The minimum and maximum of scores for whole large bowel are 0-9. The maximum of score for each part of colon is 3. 0= Unprepared colon segment with mucosa not seen due to solid stool that cannot be cleared. 1= Portion of mucosa of the colon segment seen, but other areas of the colon segment not well seen due to staining, residual stool and/or opaque liquid. 2 = Minor amount of residual staining, small fragments of stool and/or opaque liquid, but mucosa of colon segment seen well. 3 = Entire mucosa of colon segment seen well with no residual staining, small fragments of stool or opaque liquid

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014110919881N1**

Registration date: **2014-12-04, 1393/09/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-04, 1393/09/13

Registrant information

Name

Hazhir Javaherizadeh

Name of organization / entity

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Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

This study was supported by Shiraz University of Medical Sciences

Expected recruitment start date

2014-12-01, 1393/09/10

Expected recruitment end date

2015-06-01, 1394/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the three one day colon preparation methods with oral PEG, oral PEG plus bisacodyl suppository and oral PEG plus saline enema for colonoscopy in children

Public title

Comparison of three different methods for bowel preparation

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: All children aged 2-21 years old who have indication for colonoscopy
Exclusion criteria: Parental disagreement; History of previous gastrointestinal surgery; History of previous bowel preparation in 2 weeks; Uncooperative patients

Age

From **2 years** old to **21 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand St.,
Shiraz, Iran

City

Shiraz

Postal code

Approval date

2014-11-02, 1393/08/11

Ethics committee reference number

CT-P-9365-6845

Health conditions studied

1

Description of health condition studied

Bowel preparation before colonoscopy

ICD-10 code

K62.5

ICD-10 code description

Haemorrhage of anus and rectum

2

Description of health condition studied

Bowel preparation- Ulcerative colitis

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes

1

Description

Boston Bowel Preparation Scale

Timepoint

During colonoscopy

Method of measurement

With observation according to validated scale

Secondary outcomes

1

Description

None

Timepoint

None

Method of measurement

None

Intervention groups

1

Description

Group I: Oral polyethylene glycol will be used for bowel preparation starting from 4 pm one day before colonoscopy. For children weighed ≥ 45 kg, 280 gr of polyethylene glycol will be used. For children < 45 kg, 140 gram of PEG will be used.

Category

Treatment - Drugs

2

Description

Group II. Oral polyethylene glycol will be used for bowel preparation starting from 4 pm one day before colonoscopy. For children weighed ≥ 45 kg, 280 gr of polyethylene glycol will be used. For children < 45 kg,

140 gram of PEG will be used. In addition to PEG, bisacodyl suppository (5mg) will be used three times (at 8hr interval) in the day before colonoscopy.

Category

Treatment - Drugs

3

Description

Group III: Oral polyethylene glycol will be used for bowel preparation starting from 4 pm one day before colonoscopy. For children weighed ≥ 45 kg, 280 gr of polyethylene glycol will be used. For children < 45 kg, 140 gram of PEG will be used. Normal saline (500 cc) at 12 hr interval in two dosage will be used.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dept. of Pediatric Gastroenterology, Namazi Hospital

Full name of responsible person

Hazhir Javaherizadeh

Street address

Dept. of Pediatric Gastroenterology, Namazi Hospital, Namazi Sq, Shiraz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Street address

Dept. of Pediatric Gastroenterology, Namazi Hospital

City

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Hazhir Javaherizadeh

Position

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Other areas of specialty/work

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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