

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of clear liquid versus low fiber diet regimen for colonoscopy preparation 2-14 years old children referred to Amirkola pediatric hospital

Protocol summary

Study aim

Comparison of clear liquid versus low fiber diet regimen for colonoscopy preparation

Design

A randomized, blinded, controlled clinical trial with a parallel group design of 100 patients.

Settings and conduct

In this study, patients are divided two groups: one group receives a clear liquid diet and pidrolax powder and bisacodyl tablets, and the second group receives a low-fiber diet and pidrolax powder and bisacodyl tablets. The next morning, colonoscopy is performed by a pediatric gastroenterologist. Resident and gastroenterologist assess intestinal preparation with Boston bowel preparation.

Participants/Inclusion and exclusion criteria

2-14 years old children referred to Amirkola pediatric hospital Heart disease, renal disease, metabolic disease, allergy to poly ethylene glycol

Intervention groups

Comparison of clear liquid versus low fiber diet regimen
Clear liquid: chicken water, broth, soup, fruit juice, tea
Low fiber: milk, dairy, soft bread, honey

Main outcome variables

Quality of bowel cleansing, gastrointestinal complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210505051185N1**

Registration date: **2021-05-22, 1400/03/01**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-22, 1400/03/01**

Update count: **0**

Registration date

2021-05-22, 1400/03/01

Registrant information

Name

Setareh Kamel

Name of organization / entity

The university of babol

Country

Iran (Islamic Republic of)

Phone

+98 11 4227 3143

Email address

dsenshenas@chmail.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clear liquid versus low fiber diet regimen for colonoscopy preparation 2-14 years old children referred to Amirkola pediatric hospital

Public title

Comparison of clear liquid and low fiber diet regimen for colonoscopy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Children 2 to 14 years old are candidates for colonoscopy referred to Amirkola Children's Hospital

Exclusion criteria:

Heart disease, renal disease, metabolic disease, allergy to poly ethylene glycol

Age

From **2 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants do not know how patients choose to receive the diet.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of babol University of Medical Sciences

Street address

Shafizade Ave., Emam Blvd., Babol Town

City

Babol

Province

Mazandaran

Postal code

4766161685

Approval date

2021-03-13, 1399/12/23

Ethics committee reference number

IR.MUBABOL.REC.1399.505

Health conditions studied

1

Description of health condition studied

Colonoscopy preparation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Intestinal cleansing

Timepoint

After colonoscopy

Method of measurement

Boston bowel preparation

Secondary outcomes

1

Description

Regimen complications

Timepoint

After colonoscopy

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group:Before colonoscopy, One group receive clear liquids diet and Pidrolax powder 2 grams per kilogram of weight made by Sepidaj Karaj factory and bisacodyl tablets. The next morning, colonoscopy is performed by a gastroenterologist using the Olympus CE-H17.L machine made in Japan. After a colonoscopy, the doctor and nurse assess the bowel preparation by Boston Bowel preparation score.

Category

Rehabilitation

2

Description

Intervention group:Before colonoscopy, Second group receive low fiber diet and Pidrolax powder 2 grams per kilogram of weight made by Sepidaj Karaj factory and bisacodyl tablets. The next morning, colonoscopy is performed by a gastroenterologist using the Olympus CE-H17.L machine made in Japan. After a colonoscopy, the doctor and nurse assess the bowel preparation by Boston Bowel preparation score.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkola pediatric hospital

Full name of responsible person

Setareh kamel

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Sanaz mehrabani tabari

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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

Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Setareh Kamel

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Setareh kamel

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

Sanaz mehrabani tabari

Position

Associated professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

The main outcome information can be shared

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Pediatric doctors

Under which criteria data/document could be used

For colonoscopy preparation

From where data/document is obtainable

Setareh kamel

What processes are involved for a request to access data/document

Inform the resident and the permission of the above gastroenterology specialist

Comments