Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Iran (Islamic Republic of)

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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
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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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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