Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of Polyethylene Glycol (Single dose vs divided dose) in Treatment of Functional Constipation in Children

Protocol summary

Study aim

This study aimed to compare different regimens of Polyethylene Glycol (PEG, single dose vs. divided dose) in the treatment of functional constipation among children aged 4-15 years.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 80 patients. simple randomization has been used.

Settings and conduct

In this study, based on a pilot project and two blind heads, 80 children aged 4-15 years referred to Imam Reza Specialized and Subspecialty Clinic of Shiraz University of Medical Sciences, who were diagnosed with Functional Chronic Constipation based on their history and physical examination. They will be investigated after obtaining informed consent from the parents

Participants/Inclusion and exclusion criteria

The inclusion criteria of the study were aging 4-15 years, suffering from Functional Constipation based on the Rome IV criteria, and having complete information and follow-up. The exclusion criteria were non-compliance with the treatment, having organic causes of constipation, other organic problems and having used lactulose or other laxatives

Intervention groups

In the experimental group, 40 children used the single dose of polyethylene glycol as a treatment for constipation and in the control group, 40 children used the divided dose of polyethylene glycol as a treatment for constipation.

Main outcome variables

Defecation less than or equal to two times a week, Fecal incontinence equal or more than once a week, History of excessive stool retention, History of hard or painful defecation, Large fecal mass in the rectum, History of thick stools that may block the toilet, Appetite disorder, Bad Breath, Abdominal pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090908002434N9**
Registration date: **2021-10-12, 1400/07/20**
Registration timing: **prospective**

Last update: **2021-10-12, 1400/07/20**
Update count: **0**

Registration date

2021-10-12, 1400/07/20

Registrant information

Name
Mohammad Hadi Imanieh
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
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Email address
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-22, 1400/07/30

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of Polyethylene Glycol (Single dose vs divided dose) in Treatment of Functional Constipation in Children

Public title
Comparison of the effect of Polyethylene Glycol (Single dose vs divided dose) in Treatment of Functional Constipation in Children

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The children aged 4 to 15 years who had functional constipation on the base of Rome IV criteria. The patients which their information and follow ups were complete.

Exclusion criteria:

Age
From **4 years** old to **15 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done in a block method with a block size of 8. For each of the 10 possible cases for a block of eight, random numbers are selected between 1 and 10, and the treatment allocation list is specified according to each number. To execute the generated random sequence, the method of hiding encoded boxes or cans is used. In this method, the cans are numbered in a random sequence and inside the boxes, the desired intervention (drug) or a sheet on which the random allocation is written, is provided to the executor with the condition that the boxes are completely sealed. The researcher assigns patients to the standard intervention and treatment group based on the order of patients' entrance. Tool: In order to execute a random sequence on the study participants, block randomization with the block size of 8 will be created. How to make: Random selection of blocks and reading of letters from right to left will be done by the method of boxes numbered in random sequence. The cans are the same weight and shape and will be prepared by an independent researcher.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this double-blind study, polyethylene glycol syrup was used as a divided dose in the control group and a single dose in the experimental group. For this purpose, new patients referred to Imam Reza Clinic of Shiraz University of Medical Sciences after examination and diagnosis of constipation, The prescription sheet says the title of the medicine to treat constipation. The patient's initial information is recorded by staff who are also blind, and then the patient is referred to the clinic pharmacy for medication based on a table of block randomization with the block size of 8 .

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Zand Blvd

City
Shiraz

Province
Fars

Postal code
7134874853

Approval date
2019-01-29, 1397/11/09

Ethics committee reference number
IR.SUMS.MED.REC.1397.498

Health conditions studied

1

Description of health condition studied
Constipation

ICD-10 code
K59.0

ICD-10 code description
Constipation

Primary outcomes

1

Description
Defecation less than or equal to two times a week

Timepoint
Start treatment, one week later, three weeks later, six weeks later, twelve weeks later

Method of measurement
Questionnaire

2

Description
History of stool retention
Timepoint
Start treatment, one week later, three weeks later, six weeks later, twelve weeks later
Method of measurement
Questionnaire

3

Description
History of hard or painful defecation
Timepoint
Start treatment, one week later, three weeks later, six weeks later, twelve weeks later
Method of measurement
Questionnaire

4

Description
History of thick stools that may block the toilet
Timepoint
Start treatment, one week later, three weeks later, six weeks later, twelve weeks later
Method of measurement
Questionnaire

5

Description
Abdominal pain
Timepoint
Start treatment, one week later, three weeks later, six weeks later, twelve weeks later
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: polyethylene glycol was administered orally at a dose of 1 cc/kg body weight from a solution containing 40% without electrolytes (0.4 g/kg) on a single dose basis. Increasing the dose up to 2 cc/kg body weight (0.8 g/kg) daily was allowed by the caregiver for the children who did not improve after at least three days of treatment. It should be noted that the use of other laxatives was not allowed during the study period. In addition, if the patients did not defecate for more than three days, they were referred to a physician. A proper toilet training with regular stool sittings for 5-10 minutes was advised after each meal. Furthermore, the patients and their parents were asked to keep a stool diary during the 12 weeks of treatment, with weekly reports of the frequency of bowel movements, stool consistency measured through the Bristol Stool Form Scale , episodes of fecal incontinence, and presence of the associated gastrointestinal symptoms such as nausea, vomiting, flatulence, abdominal pain, painful defecation, and rectal bleeding.
Category
Treatment - Drugs

2

Description
Control group: 40 children use polyethylene glycol in divided dose as a treatment for constipation
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Specialized and Subspecialty Clinic of Shiraz University of Medical Sciences
Full name of responsible person
Sajad Hekmati
Street address
Namazi Square, Shiraz, Zand St.,Fars Province,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Shiraz university of medical sciences(central building), Zand Street, Shiraz, Fars
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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
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
Shiraz University of Medical Sciences
Full name of responsible person
Naser Honar
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

Contact
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پزشکی عمومی
Latest degree
Medical doctor
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safarpourh@sums.ac.ir

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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
After the research and publication of the article, information about the main outcome and the interventions will be shared.
When the data will become available and for how

long

At the end of the study since 2021

To whom data/document is available

All physicians and researchers related to the field of pediatrics

Under which criteria data/document could be used

For therapeutic and research use, information will be provided to all physicians and researchers

From where data/document is obtainable

Shiraz Namazi Hospital, Pediatric's Department Office, Pediatric Gastroenterology Department

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

By referring to Shiraz Namazi Hospital, Pediatric's Department Office, Pediatric Gastroenterology Department

Comments