

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

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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

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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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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

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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

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