

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Comparison of the effect of polyethylene glycol syrup and lactulose syrup in children aged 1 to 15 years with chronic functional constipation

Protocol summary

2022-09-05, 1401/06/14

Study aim

Determination of the effectiveness of polyethylene glycol syrup in comparison with lactulose syrup in children with chronic functional constipation

Design

A double-blind clinical trial was performed on 100 children aged 1 to 15 years randomly divided into two groups of 50 patients. Each group was randomly assigned to polyethylene glycol and lactulose syrup.

Settings and conduct

A double-blind clinical trial was performed on 100 children with chronic functional constipation aged 1 to 15 years randomly divided into two groups of 50 patients. Each group was randomly assigned to polyethylene glycol and lactulose syrup.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children with chronic functional constipation aged between 1-and 15 years old. Exclusion criteria: Children with chronic functional constipation aged between 1-and 15 years old with organic reasons.

Intervention groups

Group 1:groups A treated with lactulose syrup
Group 2:groups B treated with polyethylene glycol syrup

Main outcome variables

Daily number of defecation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171015036783N2**

Registration date: **2022-09-05, 1401/06/14**

Registration timing: **retrospective**

Last update: **2022-09-05, 1401/06/14**

Update count: **0**

Registration date

Registrant information

Name

Naghi Dara

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2225 9003

Email address

drdara49@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of polyethylene glycol syrup and lactulose syrup in children aged 1 to 15 years with chronic functional constipation

Public title

Comparison of the effect of polyethylene glycol syrup and lactulose syrup in children aged 1 to 15 years with chronic functional constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1-15 years old Chronic Functional Constipation

Exclusion criteria:

others causes of constipation

Age

From **1 year** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be examined by a gastroenterologist and rejecting the organic causes of constipation. Then will be randomly divided into two groups A and B based on randomly table.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study was performed as a double-blind clinical trial on 100 children aged 1 to 15 years old randomly divided into two groups of 50 patients. After random allocation of patients, the investigator will be assigned to each of the medicines A and B, and the treatment will be followed by the patient or the referring person according to the chosen code. The syrup prepared from both of the two drugs will be quite similar in shape, taste and other factors. Therefore, the doctor and the patients will not be aware of the blindness process.

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid beheshti university of medical science

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2019-03-06, 1397/12/15

Ethics committee reference number

IR.SBMU.RICH.REC.1398.004

Health conditions studied**1****Description of health condition studied**

chronic functional constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes**1****Description**

Daily number of defecation.

Timepoint

weekly in the first month then monthly for 3 months.

Method of measurement

bristol stool chart

Secondary outcomes**1****Description**

Daily number of soft defecation.

Timepoint

The time periods of measurement to evaluate the number of stools will be visited weekly for one month and then monthly for three months by a gastroenterologist.

Method of measurement

A researcher-made checklist will be used to evaluate the number of bowel movements. For this purpose, the checklist will be provided to the parents.

2**Description**

quality of daily defecation

Timepoint

The time periods of measurement to evaluate the quality of stool consistency based on the Bristol chart will be visited weekly for one month and then monthly for three months by a gastroenterologist.

Method of measurement

In order to evaluate the quality and consistency of stool, a researcher's checklist based on the Bristol chart will be used. For this purpose, the checklist will be provided to the parents.

Intervention groups

1

Description

Intervention group 1: In this group, polyethylene glycol syrup with a concentration of 60 percent with the same dose of 1 milligram per kilogram daily is prescribed in three divided doses after meals.

Category

Treatment - Drugs

2

Description

intervention group 2: In this group, lactose syrup with the same dose of 1 milligram per kilogram daily is administered in three doses after meals.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid children Hospital

Full name of responsible person

Naghi Dara

Street address

Mofid children Hospital, shariati street, Tehran

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15468-15514

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Fax

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Email

drdara49@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor, Bldg No.2 SBMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

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Phone

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Email

drdara49@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Naghi Dara

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

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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

Comparison of the effect of polyethylene glycol syrup and lactulose syrup in children aged 1 to 15 years with chronic functional constipation referred to gastroenterology clinic of Mofid Hospital

When the data will become available and for how long

6 month after data gathering

To whom data/document is available

All of the researcher aimed at data analyzing.

Under which criteria data/document could be used

For analyzing and using in the researchs.

From where data/document is obtainable

dr. Naghi Dara

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

Sending request via email or presence. The requesting person's authentication and ensuring the purpose of the research. Sending the data via email or presence within 10 days.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Naghi Dara

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Latest degree

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