Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Comparison of two treatment regimens of powders and syrup of polyethylene glycol 40% in the treatment of chronic functional constipation in children under 15 years

Protocol summary

Summary

The aim of this study was to compare the efficacy of a treatment regimen powder and liquid polyethylene glycol %40 polyethylene glycol in the treatment of chronic constipation in children is functional. This study is a single-blind clinical trial., 96 patients with chronic constipation problem referred to Children's Clinic . Inclusion criteria: history of large-diameter stools; Record keeping stool. Exclusion criteria: children with organic constipation; Obstructive abnormality or anorectal anorectal surgery; ROME III criteria identify children who have irritable bowel syndrome; Children over 2 weeks before entering the study received treatment for constipation; Children with mental retardation or metabolic diseases such as hypothyroidism; Children with Hirschsprung's disease or spinal cord anomalies or anorectal pathology. The children selected by convenience sampling and randomly placed in two groups. The first group will receive polyethylene glycol powder and the second group syrup of 40% polyethylene glycol for two months. At the end of the study, children who are considered constipation treatment has been improved

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013120415530N3**
Registration date: **2015-12-27, 1394/10/06**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-12-27, 1394/10/06

Registrant information

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Karamali Kasiri
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Shahrekord University of Medical sciences.
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Recruitment status

Recruitment complete

Funding source

Shahrekord University Of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two treatment regimens of powders and syrup of polyethylene glycol 40% in the treatment of chronic functional constipation in children under 15 years

Public title

Comparison of two treatment regimens of powders and syrup of polyethylene glycol 40% in the treatment of chronic functional constipation in children under 15 years

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: history of large-diameter stools; Record keeping stools Exclusion criteria: children with organic constipation; Obstructive abnormality or anorectal anorectal surgery; ROME III criteria identify children who have irritable bowel syndrome; Children over 2 weeks before entering the study received treatment for constipation; Children with mental retardation or metabolic diseases such as hypothyroidism; Children with Hirschsprung's disease or spinal cord anomalies or pathology anorectal

Age
To **15 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Shahrekord, Shahrekord University of Medical Sciences

City
Shahrekord

Postal code

Approval date
2015-08-30, 1394/06/08

Ethics committee reference number
IR.Skums.REC.1394.91

Health conditions studied

1

Description of health condition studied
constipation

ICD-10 code
K59.0

ICD-10 code description
conctipation

Primary outcomes

1

Description
defication

Timepoint
two months

Method of measurement
chek list

Secondary outcomes

empty

Intervention groups

1

Description
The first group polyethylene glycol powder orally for 70 grams in a liter of water, grams per kilogram of body weight will receive daily for a period of two weeks .

Category
Treatment - Drugs

2

Description
The second group polyethylene glycol 40% in edible syrup for 2/5 cc kg of body weight daily will receive for two weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahrekord Hajar hospital

Full name of responsible person

Street address

City
Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research , Shahrekord University of Medical Sciences

Full name of responsible person
Dr.Solati Kamal

Street address
Shahrekord, Shahrekord University of Medical Sciences
City
Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research , Shahrekord University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty