

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison the effects of Psyllium seed husk powder Vs. Polyethylene glycol with and without probiotics in functional constipation of 2 to 10 year-old children

Protocol summary

Summary

Objective: To compare the effects of Psyllium vs Polyethylene glycol with and without probiotics in pediatric functional constipation. Study design: Parallel triple-blind randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers. Inclusion criteria: Two to ten-year-old children with functional constipation, diagnosed based on the ROME III criteria, referred to children's clinic of Shahid Beheshti hospital. Exclusion criteria: Children beyond 2 and over 10 years old; use of other drugs that can cause constipation or diarrhea; or history of using pidrolax and probiotic in the last year. The subjects of the study: Children referred to children's clinic of Shahid Beheshti hospital. The sample size: 160 subjects will be divided into four groups of 40. The study duration: July 2017 to July 2018. Intervention of the study: Patients after receiving testimonial from their parents will be divided into 4 groups. Group one will receive polyethylene glycol, group two polyethylene glycol with probiotics, group three Psyllium and group four Psyllium with probiotics, all manufactured in the same sachets by Takgene zist company, 0.7 gr/kg in the form of water solution daily for 8 weeks. The patients will be followed up for 8 weeks. Primary outcomes: Assessing response to treatment with filling ROME III criteria based questionnaire by parents after 8 weeks of intervention, including frequency of defecation, defecation without pain and hardness, frequency of incontinence and drug admission in four groups. Secondary outcomes: Early relapse of constipation, according to ROME III criteria, after the end of intervention by filling the questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013021112437N1**

Registration date: **2017-08-25, 1396/06/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-25, 1396/06/03

Registrant information

Name

Mohsen Taghizadeh

Name of organization / entity

Kashan 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

Takgene zist pharmacy company

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of Psyllium seed husk powder Vs.

Polyethylene glycol with and without probiotics in functional constipation of 2 to 10 year-old children

IR.KAUMS.REC.1395.113

Public title

Effects of Psyllium seed husk powder vs. Polyethylene glycol on constipation in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Two to ten years old children who refer to children's clinic of Shahid Beheshti hospital with functional constipation, diagnosed based on the ROME III criteria. Exclusion criteria: Children beyond 2 and over 10 years old; use of other drugs that can cause constipation or diarrhea; or history of using pidrolax and probiotic in the last year.

Age

From **2 years** old to **10 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Study design: Parallel triple-blind randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, Ghotbe Ravandi Blvd, Kashan, Iran

City

Kashan

Postal code

Approval date

2017-01-18, 1395/10/29

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Constipation

ICD-10 code

k59.0

ICD-10 code description

Other functional intestinal disorders

Primary outcomes

1

Description

Defecation frequency

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Recorded through questionnaires filled by parents

2

Description

Defecation without pain

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Recorded through questionnaires filled by parents

3

Description

Drug admission

Timepoint

8 weeks after intervention

Method of measurement

Recorded through questionnaires filled by parents

4

Description

Defecation incontinency

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Recorded through questionnaires filled by parents

5

Description

Adverse effects of drugs

Timepoint

8 weeks after intervention

Method of measurement

Recorded through questionnaires filled by parents

Secondary outcomes

1

Description

Early constipation relapse discontinue medication

Timepoint

4 weeks after end of treatment

Method of measurement

Questionnaire that filling with parents

Intervention groups

1

Description

Intervention group 1: This group will receive one 7 gr sachet of polyethylene glycol, manufactured by Takgene zist, 0.7 gr/kg/day soled in 150 cc water, orally, for 8 weeks.

Category

Treatment - Drugs

2

Description

Intervention group 2: This group will receive one 7 gr sachet of polyethylene glycol with probiotics, manufactured by Takgene zist, 0.7 gr/kg/day soled in 150 cc water, orally, for 8 weeks.

Category

Treatment - Drugs

3

Description

Intervention group 3: This group will receive one 7 gr sachet of Psyllium, manufactured by Takgene zist, 0.7 gr/kg/day soled in 150 cc water, orally, for 8 weeks.

Category

Treatment - Drugs

4

Description

Intervention group 4: This group will receive one 7 gr sachet of Psyllium with probiotics, manufactured by Takgene zist, 0.7 gr/kg/day soled in 150 cc water, orally, for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Dr. Mohammadreza Sharif

Street address

Shahid Beheshti Hospital, Ghotbe Ravandi Blvd,
Kashan, Iran

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Kashan University of
Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

Kashan University of Medical Sciences, Ghotbe
Ravandi Blvd, Kashan, Iran

City

Kashan

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 of Kashan 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

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Sharif

Position

Associate Professor, Pediatric Infectious Diseases
Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Associate Professor, PhD in nutrition

Other areas of specialty/work

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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