

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The comparison between effect polyethylene glycol (PEG) Along with Bacillus coagulans (probiotic) with effect polyethylene glycol (PEG) in treatment of functional constipation in Childrens referred to pediatric gastroenterology clinic of Shiraz University of Medical Sciences

Protocol summary

Summary

Abstract : The purpose was to compare the effect of probiotic with polyethylene glycol and polyethylene glycol alone for the treatment of functional constipation in children. Design: In this study children with functional constipation randomly allocated into two groups. To the first group was given polyethylene glycol and second group was given probiotic and polyethylene glycol. After 6 weeks, probiotic was added to group1 and removed from group2 medication. The study fallowed for more six weeks. The results of 4th week were compared with 1th week, and the results of 10th week were compared with 7th week in each groups. The data of 4th and 10th weeks were also compared between both groups. How do: Number of 80 children with functional constipation were enrolled in the study (40 for each group). Before treatment, basic information (stool frequency, stool consistency, fecal incontinence, abdominal pain, pain during defecation) were recorded. During the study, daily symptoms were recorded by the standard form. The data collected during the study were analyzed by SPSS software. Participants including major eligibility criteria: Inclusion criteria: children with functional constipation (Rome III criteria) Exclusion criteria: use of other medication for functional constipation except polyethylene glycol in 1 last month; The presence of organic cause; Dissatisfaction of parents or Patient Intervention: Use of probiotic of Bacillus Coagulans as adjuvant treatment of functional constipation by adding to polyethylene glycol The main outcome variable: The mean stool frequency, stool consistency, fecal incontinence, abdominal pain, pain during defecation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812222434N3**

Registration date: **2015-05-10, 1394/02/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-10, 1394/02/20

Registrant information

Name

Mohammad Hadi Imanieh

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1647 4298

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Recruitment status

Recruitment complete

Funding source

vice chancellor for research shiraz university of medical sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-04-17, 1393/01/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between effect polyethylene glycol (PEG) Along with Bacillus coagulans (probiotic) with effect polyethylene glycol (PEG) in treatment of functional constipation in Childrens referred to pediatric gastroenterology clinic of Shiraz University of Medical Sciences

Public title

Comparison of effect of probiotic with polyethylene glycol,with polyethylene glycol alone in the treatment of functional constipation in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:All pediatric patient with constipation that fulfilled Rome III criteria for functional constipation without any treatment;All pediatric patient with constipation that fulfilled Rome III criteria for functional constipation without clinical response to polyethylene glycol (PEG) Exclusion criteria:patients received other drugs for constipation except polyethylene glycol (PEG); The presence of organic cause; Dissatisfaction of parents or Patient

Age

From **1 month** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences(central building), Zand Street, Shiraz, Fars

City

Shiraz

Postal code

Approval date

2013-09-28, 1392/07/06

Ethics committee reference number

ct-p-9355-5585

Health conditions studied

1

Description of health condition studied

constipation

ICD-10 code

k59.0

ICD-10 code description

Retention,retained-fecal

Primary outcomes

1

Description

stool frequency

Timepoint

1th week.4thweek.7thweek and 10th week

Method of measurement

recorded through questionnaires

2

Description

stool incontinence

Timepoint

1th week.4thweek.7thweek and 10th week

Method of measurement

recorded through questionnaires

3

Description

stool consistency

Timepoint

1th week.4thweek.7thweek and 10th week

Method of measurement

recorded through questionnaires

4

Description

abdominal pain

Timepoint

1th week.4thweek.7thweek and 10th week

Method of measurement

recorded through questionnaires

5

Description

pain on defecation

Timepoint

1th week.4thweek.7thweek and 10th week

Method of measurement

recorded through questionnaires

Secondary outcomes

1

Description

drug adverse effects and clinical response

Timepoint

6th week and 12th week

Method of measurement

recoded through questionnaires

2

Description

Evaluation of Clinical response on stool frequency

Timepoint

1th week.4thweek.7thweek and 10th week

Method of measurement

recoded through questionnaires

3

Description

Evaluation of Clinical response on Fecal incontinence

Timepoint

1th week.4thweek.7thweek and 10th week

Method of measurement

recoded through questionnaires

4

Description

Evaluation of Clinical response on stool Consistency

Timepoint

1th week.4thweek.7thweek and 10th week

Method of measurement

recoded through questionnaires

5

Description

Evaluation of clinical response of pain during defecation

Timepoint

1th week.4thweek.7thweek and 10th week

Method of measurement

recoded through questionnaires

6

Description

Evaluation of Clinical response on abdominal pain

Timepoint

1th week.4thweek.7thweek and 10th week

Method of measurement

recoded through questionnaires

Intervention groups

1

Description

PEG solution 40% : 0.5gr/kg/dose TID Cap probiotic:
1.5*10⁹ CFU TID

Category

Treatment - Drugs

2

Description

PEG solution 40% : 0.5gr/kg/dose TID for 6 week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric GI clinic, Imam Reza clinic

Full name of responsible person

Ali keshtkari

Street address

Imam Reza clinic, Namazi Square, Zand street, Shiraz,
Fars

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences, vice chancellor
for research

Full name of responsible person

Dr Basir Hashemi

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Shiraz university of medical sciences(central
building), Zand Street, Shiraz, Fars

City

Shiraz

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, vice chancellor for
research

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

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Person responsible for general inquiries

Contact

Name of organization / entity

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Position

Fellowship of Pediatric Gastroenterology

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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