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)
Phone
+98 71 1647 4298
Email address
imaniehm@sums.ac.ir

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
Street address
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

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Ali Keshtkari
Position
Fellowship of Pediatric Gastroenterology
Other areas of specialty/work
Street address
Pediatric GI ward, Nammazi Hospital, Shiraz, Fars
City
Shiraz
Postal code
Phone
00
Fax
Email
keshtkari@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Hadi Imanieh
Position
Professor of Pediatric Gastroenterology
Other areas of specialty/work
Street address
Pediatric GI ward, Department of Pediatric, Nammazi Hospital, Shiraz, Fars
City
Shiraz
Postal code
Phone
+98 71136474298
Fax
Email
imaniehm@sums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Ali Keshtkari
Position
Fellowship of Pediatric Gastroenterology
Other areas of specialty/work
Street address
Pediatric GI ward, Nammazi Hospital, Shiraz, Fars
City
Shiraz
Postal code
Phone
00
Fax
Email
keshtkari@sums.ac.ir
Web page address

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