Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of therapeotic effect of probiotic with PEG in children functional constipation.

Protocol summary

Summary

This study aimed to investigate the therapeutic effect of probiotic Bacillus Plyatylnglykvl and Prhbyvtyk Kvagvlans and Bifidobacterium probiotics is designed to stimulate growth. In this double blind clinical trial , 120 children 2-16 years old with functional chronic constipation referred to Amir Kabir hospital of Arak according to inclusion criteria : no other cell disease and exclusion criteria : children with a diagnosis of IBS ; mentally retarded children or metabolic disease , or spinal anomalies in children with Hirschsprung's disease or anorectal pathology , children with a history of stomach or intestinal surgery were enrolled and received at least 2-3 days to constipation enema liquid paraffin as the primary fixed and randomly divided into three groups ethylene Polyphlore glycol + placebo (n = 40) , and the prebiotics + placebo (n = 40) and polyethylene glycol (PEG) + probiotic (n = 40) at a dose of gr / kg / day 7/0 are divided .Treatment will continue for 6 weeks. Defecation frequency per week, stool consistency, frequency of having abdominal pain and painful defecation, constipation side effects such as nausea and vomiting, headache baseline and after it is recorded. These variables as well as possible side effects of drugs used in the study and treatment success rates are compared between the three groups before and after the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112415511N1**
Registration date: **2013-12-13, 1392/09/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-12-13, 1392/09/22

Registrant information

Name
Dr. Mojtaba Hashemi
Name of organization / entity
Arak University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 863134719
Email address
s.hashemi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Council of Arak University of Medical Sciences

Expected recruitment start date

2013-08-21, 1392/05/30

Expected recruitment end date

2014-07-21, 1393/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeotic effect of probiotic with PEG in children functional constipation.

Public title

Comparison of therapeotic effect of probiotic with PEG in children functional constipation.

Purpose

Treatment

Inclusion/Exclusion criteria

nclusion criteria: children 2-16 years of age with chronic

functional constipation associated with any disease.Exclusion criteria: Children diagnosed with IBS criteria ROME III;Treatment of constipation in the two weeks prior to study entry; Children with mental retardation or metabolic diseases (eg, hypothyroidism); Children with Hirschsprung's disease or anorectal anomalies injury or pathology; Children with a history of stomach or intestinal surgery; Children under medical treatment affecting the GI such as cisapride; Motilium, erythromycin and loperamide

Age
From **2 years** old to **16 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Arak University Medical Sciences

Street address
Hoda Elm Street, Amirkabir, Arak

City
Arak

Postal code

Approval date
2013-08-21, 1392/05/30

Ethics committee reference number
14- 151 - 92

Health conditions studied

1

Description of health condition studied
Constipation

ICD-10 code
K59.0

ICD-10 code description
Constipation

Primary outcomes

1

Description
Defecation frequency per week

Timepoint
Baseline and then

Method of measurement
Questionnaire

2

Description
Stool consistency

Timepoint
Baseline and then

Method of measurement
Questionnaire

3

Description
Read Ndad having abdominal pain and painful defecation

Timepoint
Baseline and then

Method of measurement
Questionnaire

Secondary outcomes

1

Description
Headache

Timepoint
Baseline and then

Method of measurement
Checklist

2

Description
Nausea and vomiting

Timepoint
Baseline and then

Method of measurement
Checklist

Intervention groups

1

Description
Group 1: Polyethylene glycol (PEG) + placebo (n = 40)

Category
Placebo

2

Description
Group 2: Probiotic + placebo (n = 40)
Category
Treatment - Drugs

3

Description
Group 3: polyethylene glycol (PEG) + probiotic (40)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkabir Hospital Arak
Full name of responsible person
Dr. Hashemi Mojtaba
Street address
Aamirkabir hospital - arak
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Hekmatpoo Davood
Street address
Hoda Elm Street, Hospital Amirkabir, Arak
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Marjan Habibi
Position
Resident of General Pediatric Diseases
Other areas of specialty/work
Street address
Hoda Elm Street, Hospital Amirkabir, Arak
City
Arak
Postal code
Phone
+86 33134716
Fax
Email
mary_jane612000@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mojtaba Hashemi
Position
Specialty of Pediatric Cardiology
Other areas of specialty/work
Street address
Amirkabir Hospital- Hoda elm street- Arak
City
Arak
Postal code
Phone
+98 86 3313 4716
Fax
Email
mojtaba53hashemi@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Marjan Habibi
Position
Resident of General Pediatric Diseases
Other areas of specialty/work
Street address
Hoda Elm Street,Hospital Amirkabir, Arak
City
Arak
Postal code
Phone
+86 33134716

Fax

Email

mary_jane612000@yahoo.com

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