# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

06 Nov 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
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Arak University of Medical Sciences
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**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**
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## Person responsible for scientific inquiries

**Contact**
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**Full name of responsible person**
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## Person responsible for updating data

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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*