

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The effect of probiotic use in children with functional constipation

#### Protocol summary

##### Study aim

Determining and comparing the number of bowel movements during a week and the number of unwanted bowel movements during the day and the number of painful bowel movements during a week and the number of cases of abdominal pain during a week and the consistency of stool in the study groups

##### Design

Double-blind clinical trial, with factorial groups, phase 3 on 150 patients

##### Settings and conduct

This study is a double-blind clinical trial study performed on children with chronic functional constipation referred to the pediatric clinics of Shariati and Gharzi medical centers in Isfahan. All forms of medicine used are labeled the same and only labeled by the consulting pharmacist. First, the necessary explanations on how to implement the plan are provided to the parents, and then the informed consent form is completed by the child's legal guardian. Then, 150 patients with chronic functional constipation are selected based on inclusion and non-inclusion criteria and are randomly divided into 2 groups of 75 people. Information is recorded in a questionnaire by asking parents. Forms are anonymous and coded. Is filled and the treating physician does not witness this process.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: chronic functional constipation, age 2 to 15 years Conditions of non-entry: diseases of the large and small intestine, allergy to polyethylene glycol, intestinal obstruction, kidney or heart failure

##### Intervention groups

The first group (A) consumes 1 g / kg body weight of water-soluble polyethylene glycol powder daily and the second group (B) consumes one sachet of Kidi Lactate probiotic powder and 1 g / kg body weight of water-soluble polyethylene glycol daily.

##### Main outcome variables

Number of bowel movements; Number of unwanted bowel movements; Number of painful bowel movements;

Number of abdominal pain; Determination and comparison of fecal consistency

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210525051398N1**

Registration date: **2021-05-30, 1400/03/09**

Registration timing: **prospective**

Last update: **2021-05-30, 1400/03/09**

Update count: **0**

##### Registration date

2021-05-30, 1400/03/09

##### Registrant information

##### Name

Pegah Kaveh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 2222 1761

##### Email address

pgh.kaveh@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-31, 1400/03/10

##### Expected recruitment end date

2021-09-22, 1400/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of probiotic use in children with functional constipation

## Public title

The effect of probiotic use in children with functional constipation

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Children with functional constipation Between 2 to 15 years old

### Exclusion criteria:

Diseases of the large and small intestine Sensitivity to polyethylene glycol Intestinal obstruction Kidney or heart failure

## Age

From **2 years** old to **15 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

## Sample size

Target sample size: **150**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Limited randomization with 75-person blocks is performed by the consulting pharmacist using a random number table of Random Allocation Software.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

This study is a double-blind clinical trial study performed on children with chronic functional constipation referred to the pediatric clinics of Shariati and Gharzi medical centers in Isfahan. All forms of medicine used are labeled the same and only labeled by the consulting pharmacist. First, the necessary explanations on how to implement the plan are provided to the parents, and then the informed consent form is completed and signed by the child's legal guardian. The personal details of the children participating in the project will be confidential. The required information will be collected by asking the parents and recorded in the relevant questionnaire. The forms are filled in anonymously and in coded form and the treating physician does not witness this process.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Islamic Azad University - Shahrood Branch

##### Street address

No. 5, Azar 17 Alley, Panje Azar St, Jaber Ansari Ave

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8138958638

#### Approval date

2020-09-30, 1399/07/09

#### Ethics committee reference number

IR.IAU.SHAHROOD.REC.1399.030

## Health conditions studied

### 1

#### Description of health condition studied

Functional Constipation

#### ICD-10 code

K59.0

#### ICD-10 code description

Constipation

## Primary outcomes

### 1

#### Description

Number of bowel movements during one week

#### Timepoint

Number of bowel movements during one week at the beginning of the study (before the intervention) and 7 and 14 days after taking probiotics

#### Method of measurement

The required information is collected by asking the parents and recorded in the prepared questionnaire

### 2

#### Description

Number of unwanted bowel movements during the day

#### Timepoint

Number of unwanted bowel movements during the day at the beginning of the study (before the intervention) and 7 and 14 days after taking probiotics

#### Method of measurement

The required information is collected by asking the parents and recorded in the prepared questionnaire

### 3

#### **Description**

Number of painful bowel movements in a week

#### **Timepoint**

Number of painful bowel movements during one week at the beginning of the study (before the intervention) and 7 and 14 days after the start of probiotic use

#### **Method of measurement**

The required information is collected by asking the parents and recorded in the prepared questionnaire

### 4

#### **Description**

The number of times abdominal pain occurs in a week

#### **Timepoint**

The frequency of abdominal pain during one week at the beginning of the study (before the intervention) and 7 and 14 days after taking probiotics

#### **Method of measurement**

The required information is collected by asking the parents and recorded in the prepared questionnaire

### 5

#### **Description**

Determination and comparison of fecal consistency

#### **Timepoint**

Determination and comparison of fecal consistency at the beginning of the study (before the intervention) and 7 and 14 days after probiotic use

#### **Method of measurement**

The required information is collected by asking the parents and recorded in the prepared questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: The first group is dissolved Kidi Lactate probiotic powder in a dose of 1 sachet per day in water and 1 g / kg body weight of water-soluble polyethylene glycol powder is given daily for 2 weeks. At first, it is recommended to consume less food. High fat and dairy and recommend eating more fruits, vegetables and high fiber foods. Parents are also given the necessary training on using the toilet and encouraging their children to go to the toilet, and it is recommended that they exercise regularly and use the toilet after each meal.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: 1 g / kg body weight of water-soluble

polyethylene glycol powder is given daily for 2 weeks. Parents are also instructed in using the toilet and encouraging their children to go to the toilet, and it is recommended that they exercise regularly and use the toilet after each meal.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shariati hospital

##### **Full name of responsible person**

Pegah Kaveh

##### **Street address**

Chaharbagh bala Ave

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8173745384

##### **Phone**

+98 31 3627 2001

##### **Email**

Shariati\_isf.hos@tamin.ir

##### **Web page address**

<https://shariati-isf.tamin.ir/>

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Gharazi hospital

##### **Full name of responsible person**

Pegah Kaveh

##### **Street address**

Dr Gharazi St, Kaveh Ave

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8196973133

##### **Phone**

+98 31 3450 9901

##### **Email**

Gharazi.hos@tamin.ir

##### **Web page address**

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Islamic Azad University

##### **Full name of responsible person**

Sahebali Manafi

**Street address**

Daneshgah Blvd

**City**

Shahrood

**Province**

Semnan

**Postal code**

3619943189

**Phone**

+98 23 3239 4530

**Email**

Info@iauh-shahrood.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Islamic Azad University

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Pegah Kaveh

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

No. 5, Azar 17 Alley, Panje Azar St, Jaber Ansari Ave

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**Postal code**

8138958638

**Phone**

+98 31 3433 1295

**Fax****Email**

pgh.kaveh@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Fax****Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available