

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

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

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Full name of responsible person

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

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Full name of responsible person

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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