Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Evaluation of the effectiveness of Lactobacillus reuteri probiotic versus placebo in the treatment of functional constipation in children 3 to 18 years old

Protocol summary

Study aim

Evaluation of the effectiveness of Lactobacillus reuteri probiotic against placebo in the treatment of functional constipation in children aged 3 to 18 years

Design

Clinical trial with control group, double-blind, randomized, phase 3 on 160 patients. Used to randomize the physician to randomly deliver packets containing medication or placebo to the patient.

Settings and conduct

The study was performed in the gastrointestinal clinic of Mofid Hospital in Tehran and Besat Hospital in Hamadan in a double-blind manner (neither the physician nor the patients were aware of the contents of the sachets received by the patients regarding the presence of probiotics or placebo).

Participants/Inclusion and exclusion criteria

To enter the study, children must be over 3 years old and under 18 years old. Functional constipation is diagnosed according to Rome IV criteria. Before starting the study, people whose constipation has major causes such as Hirschsprung's disease, Bifida spine, hypothyroidism or other metabolic or renal disorders and mental retardation or other diseases related to the large and small intestine. Intestinal obstruction as well as the presence of kidney or heart failure are not included in the study

Intervention groups

A group of 80 people who accidentally received a probiotic

Main outcome variables

1. Number of bowel movements 2. Stool consistency 3. The number of Painful stools 4. abdominal pain 5. Stool incontinence 6. appetite

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150706023084N13**
Registration date: **2021-12-29, 1400/10/08**
Registration timing: **prospective**

Last update: **2021-12-29, 1400/10/08**
Update count: **0**

Registration date

2021-12-29, 1400/10/08

Registrant information

Name

MARYAM SHIEHMORTEZA

Name of organization / entity

AZAD UNIVERSITY PHARMACEUTICAL SCIENCES

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effectiveness of Lactobacillus reuteri probiotic versus placebo in the treatment of functional constipation in children 3 to 18 years old

Public title
Evaluation of the effect of Lactobacillus reuteri probiotic in functional constipation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People with functional constipation according to ROME IV criteria Diagnosis of functional constipation should be based on a pediatric gastroenterologist Age range 3 to 18 years

Exclusion criteria:
Having other underlying diseases History of allergies to the studied drugs and their accessories Use of any probiotics and prebiotics and laxatives other than study drugs and outside the study conditions

Age
From **3 years** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description
After receiving the drug and placebo packages from Farabiotic Company, 160 codes were randomly distributed between the boxes by the epidemiologist. Only the epidemiologist is aware of the type of codes and the drugs were delivered to a specialist after randomization to reach the relevant patients. Randomization was simple and individual.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is performed in a double-blind manner so that neither the physician nor the patients are aware of the contents of the sachets received by the patients based on the presence of probiotics or placebo. One group contains Lactobacillus reuteri and the other placebo and the doctor randomly give the patient a packet of the drug group. Finally, the results are reviewed and evaluated by the study evaluator by reviewing the collected data and equivalence with the package codes.

Placebo
Used

Assignment
Parallel

Other design features
This study is performed in two parts. In the first part, the studied drug (probiotic or placebo) along with polyethylene glycol is given to patients (as standard treatment) for 28 days, and in the second part, the polyethylene glycol drug is discontinued and only probiotic or placebo is given to the patient for 28 days.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Department of Pharmaceutical Sciences, Tehran Islamic Azad University of Medical

Street address
Dr Shariati Ave., Gholhak, Yakhchal Ave., Islamic Azad University of Pharmaceutical Sciences Branch

City
Tehran

Province
Tehran

Postal code
193956466

Approval date
2021-11-10, 1400/08/19

Ethics committee reference number
IR.IAU.PS.REC.1400.302

Health conditions studied

1

Description of health condition studied
functional constipation in children

ICD-10 code
K59.0

ICD-10 code description
Constipation

Primary outcomes

1

Description
Stool stiffness

Timepoint
Stool stiffness is recorded daily in the questionnaire by individuals for 56 days

Method of measurement
Review by Bristol form and registration by the participant in the questionnaire form

2

Description

number of Painful stools

Timepoint

56 days

Method of measurement

Daily record by individual

3

Description

Stool incontinence

Timepoint

56 days

Method of measurement

Daily record by individual

4

Description

abdominal pain

Timepoint

56 days

Method of measurement

Daily record by individual

5

Description

Appetite

Timepoint

56 days

Method of measurement

Daily record by individual

6

Description

Age

Timepoint

Before starting the intervention

Method of measurement

Registered by a pediatric gastroenterologist

7

Description

Sex

Timepoint

Before starting the intervention

Method of measurement

Registered by a pediatric gastroenterologist

8

Description

Duration of treatment

Timepoint

At the end of the study

Method of measurement

Registered by a pediatric gastroenterologist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: includes 80 patients who are diagnosed with functional constipation by a pediatric gastroenterologist for 28 days of probiotic Lactobacillus reuteri produced by Farabiotic Company(one sachet daily) plus polyethylene glycol as standard treatment and then next 28 days They only take probiotics. patients are generally treated with probiotics for 56 days and fills out a questionnaire form given to them by their doctor on a daily basis.

Category

Treatment - Drugs

2

Description

Control group: includes 80 patients diagnosed with functional constipation by a pediatric gastroenterologist for 28 days of polyethylene glycol as standard treatment with placebo sachets Contains all the ingredients in the main sachets of our probiotic medicine except the probiotic itself. they take the main drug according to the instructions, and for the next 28 days, they consume only placebo sachets. In total, they use the placebo sachets produced by Farabiotic Company for 56 days as a control group and fill in the relevant questionnaire.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children's Hospital

Full name of responsible person

Dr Naghi Dara

Street address

Mofid Children's Hospital,Shariati Avenue, Tehran, Iran.

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1551415468

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2

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Gholamreza Kalvandi
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Hamedan Shahid Motahari Boulevard, Hakma Street
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besat@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Faradaro Fanavar Mehr Company
Full name of responsible person
Mohamad Mohamadi
Street address
North Kargar Street, next to the University of Tehran dormitory, Center for the Development of Pharmaceutical Technology Units, No. 1462
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Tehran
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Tehran
Postal code
1439955991
Phone
+98 21 8835 9880
Email
info@faradaru.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Faradaro Fanavar Mehr Company
Proportion provided by this source
80
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Maryam Shiehmorteza
Position
assistant professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data are collected in the form of a questionnaire
When the data will become available and for how long
After the intervention
To whom data/document is available
Qualified persons
Under which criteria data/document could be used
Use for scientific advancement in the field under study
From where data/document is obtainable
Clinical Office of Islamic Azad University, Medical Sciences of Tehran, Faculty of Pharmacy
What processes are involved for a request to access data/document
Clinical Office of Islamic Azad University, Medical Sciences of Tehran, Faculty of Pharmacy
Comments