

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the effectiveness of *Lactobacillus reuteri* probiotics in the treatment of chronic functional abdominal pain in children aged 5 to 15 years

Protocol summary

Study aim

Determining the effectiveness of *Lactobacillus reuteri* in the treatment of functional abdominal pain in children

Design

180 children with functional abdominal pain, one group of 90 people receiving *Lactobacillus reuteri* probiotic and another 90 children as a control group, receive a placebo. This is a double-blind study. Random allocation software is used to randomize and each code is typed on the medicine package that the doctor will give the patient a complete questionnaire and description

Settings and conduct

Reuteflor packages are coded after randomization and are given to the relevant doctor in Mofid Children's hospital in Tehran and Besat in Hamedan or the private office and then to the patients. The doctor, patients, and their parents are blinded. The packages of both study groups are quite similar.

Participants/Inclusion and exclusion criteria

The boy or girl is 5 to 15 years old. Admission is based on the Rome 4 criteria. 1. Abdominal pain is persistent or almost constant. 2. Pain has nothing to do with physiological events in the body (eating, defecation, menstruation, etc.). 3. Some daily functions are lost. 4. Pain is not fake. 5. Symptoms to complement the criteria for other gastrointestinal functional disorders do not fully explain the pain. All of these criteria must be present for at least three months and the onset of symptoms at least six months before diagnosis. The child should not have an underlying disease that causes abdominal pain that is diagnosed by a pediatric gastroenterologist.

Intervention groups

A group of 90 patients receive a probiotic sachet every day for 28 days. A control group of 90 patients receive a placebo sachet with the same original packaging every day for 28 days.

Main outcome variables

Pain intensity; Pain frequency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150706023084N14**

Registration date: **2021-12-30, 1400/10/09**

Registration timing: **prospective**

Last update: **2021-12-30, 1400/10/09**

Update count: **0**

Registration date

2021-12-30, 1400/10/09

Registrant information

Name

MARYAM SHIEHMORTEZA

Name of organization / entity

AZAD UNIVERSITY PHARMACEUTICAL SCIENCES

Country

Iran (Islamic Republic of)

Phone

+98 212640056

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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 probiotics in the treatment of chronic functional abdominal pain in children aged 5 to 15 years

Public title
Evaluation of the probiotic effect of Lactobacillus reuteri in the treatment of chronic functional pain in children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Abdominal pain is persistent or almost constant Pain has nothing to do with physiological events in the body (eating, defecation, menstruation, etc.) Some daily functions are lost The pain is not fake Symptoms to complete the criteria for other gastrointestinal functional disorders do not justify complete pain All of these criteria must be present for at least three months and the onset of symptoms at least six months before diagnosis
Exclusion criteria:
The doctor determines that the child has chronic abdominal pain due to the consumption of a certain type of food (special diet) or a specific organic problem. Existence of an underlying disease that, according to the pediatric gastroenterologist, has caused abdominal pain.

Age
From **5 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: **180**

Randomization (investigator's opinion)
Randomized

Randomization description
The identical packages of probiotic sachets or placebo (identified by codes 1 or 2) are randomly distributed among the people. The doctor randomly gives the patient a pack using the lottery method.

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. The packages are identified by codes that do not show the content. In the end, the analyzer, who is the only person who knows each code's meaning, reviews and evaluates the findings.

Placebo

Used

Assignment
Parallel

Other design features

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.1400.301

Health conditions studied

1

Description of health condition studied
chronic functional abdominal pain in children

ICD-10 code
R10.4

ICD-10 code description
Other and unspecified abdominal pain

Primary outcomes

1

Description
Intensity of pain

Timepoint
Every day for 28 days

Method of measurement
Based on oucher pain scale

2

Description
Frequent pain

Timepoint
Every day for 28 days

Method of measurement
Record in the table

3

Description

Duration of treatment

Timepoint

28 days

Method of measurement

Check the questionnaire table

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Lactobacillus reuteri probiotic. 28 sachets One gram of probiotic is dissolved in sachets of water, yogurt or food (cold) every day and consumed for 28 days. Each sachet of 1 g of Reuteflor contains 300 mg of Lactobacillus reuteri lyophilized active cell (equivalent to 8×10^8 CFU). Other ingredients: maltodextrin, cornstarch, magnesium stearate, silicon dioxide, inulin and natural banana flavoring. This product is free of gluten, talc, sweetener and milk ingredients. The company manufactures probiotics and placebos is farabiotic, both of which are delivered in exactly the same shape. The doctor will give the questionnaire along with the medicine to the patient with a full explanation. Store at a cool, dry temperature (below 25 ° C). No need to store in the refrigerator.

Category

Treatment - Drugs

2

Description

Control group: Lactobacillus reuteri placebo. 28 sachets One gram of placebo dissolves one sachet in water, yogurt or food (cold) every day and is consumed for up to 28 days. Each 1 gram placebo sachet contains maltodextrin, cornstarch, magnesium stearate, silicon dioxide, inulin and natural banana flavoring. This product is free of gluten, talc, sweetener and milk ingredients. The company manufactures probiotics and placebos is farabiotic, both of which are delivered in exactly the same shape. The doctor will give the questionnaire along with the medicine to the patient with a full explanation. Store at a cool, dry temperature (below 25 ° C). No need to store in the refrigerator.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid children's Hospital

Full name of responsible person

Naghi Dara

Street address

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

City

Tehran

Province

Tehran

Postal code

1551415468

Phone

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2

Recruitment center

Name of recruitment center

Besat in Hamedan

Full name of responsible person

Gholamreza Kalvandi

Street address

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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1439955991

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Email

info@faradaru.com

Web page address

<https://farabiotic.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
70
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
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person
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Pharmacy student
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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