

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of probiotic use (*Lactobacillus reuteri*) in children between ages of 2 and 14 with chronic functional constipation; Double-blind randomized clinical trial.

Protocol summary

Study aim

1- Determining the recovery rate (relative risk) in the use of probiotics and placebo in the recovery of children with chronic constipation after 7 weeks of treatment based on ROME IV criteria 2- Determining the mean difference in the length of the treatment period in the group receiving probiotics and the placebo group 3- Determining the relative risk of drug side effects in the group receiving probiotics compared to the placebo group during the 7-week treatment period

Design

Controlled clinical trial with parallel groups, double-blind, randomized, phase 3 on 60 patients. Lottery of sealed envelopes was used for randomization.

Settings and conduct

Children admitted to the pediatric gastroenterology clinic of Imam Ali Hospital (AS) who are diagnosed with functional constipation enter the study. Each patient will randomly choose one of the sealed envelopes and open it. Inside each envelope is code A or B, based on which the person will receive medicine A or B. Only the main researcher of the research is aware of the assignment of the codes. Information on the primary endpoint (Rome IV criteria) and secondary endpoints (abdominal pain, side effects and need for rescue treatment) at visits one to six (on entry, one week later, week 3, week 5 and week 7) will be obtained and finally compared between the studied groups.

Participants/Inclusion and exclusion criteria

Children between the ages of 2 and 14 who refer to the children's clinic of Imam Ali (AS) hospital with the complaint of constipation should their parents be able to fully follow the doctor's orders and do not suffer from serious and chronic physical or mental diseases

Intervention groups

Lactobacillus lutheri probiotic recipient group placebo group

Main outcome variables

Rome IV criteria; Abdominal pain; side effects; Need for rescue treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160117026069N5**

Registration date: **2023-01-26, 1401/11/06**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-26, 1401/11/06**

Update count: **0**

Registration date

2023-01-26, 1401/11/06

Registrant information

Name

Fereshteh Ansari

Name of organization / entity

Razi Vaccine and Serum Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 26 3405 0400

Email address

ansarif@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-06-21, 1402/03/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of probiotic use (Lactobacillus reuteri) in children between ages of 2 and 14 with chronic functional constipation; Double-blind randomized clinical trial.

Public title
Evaluation of probiotic use in chronic functional constipation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Suffering from functional constipation according to Rome IV criteria Age 2 to 14 years Enforceability of orders by the child's parents
Exclusion criteria:
 Children with organic causes of constipation including celiac disease, intestinal obstruction, hypothyroidism, anorectal malformation, CF Serious chronic health problems that affect the child's ability to participate in the study, such as metabolic, heart, kidney, and liver diseases Unwanted weight loss equal to or more than 5% of the current weight during the last three months Gastrointestinal bleeding Recurrent or unexplained fever History of abdominal surgery including gastrointestinal surgery, except for appendix removal or hernia repair Simultaneous use of drugs that affect the movements of the digestive system History of increased sensitivity or allergy to experimental drugs Diagnosis of autism symptoms Severe mental problems such as bipolar disorder, schizophrenia, and severe depression Use of (SNS) or antegrade enemas during cecostomy or appendicostomy

Age
From **2 years** old to **14 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Sealed envelopes are considered as the number of patients, whose content determines which group each person belongs to. One of these envelopes is selected for each patient by lottery, and then this envelope is opened and the allocation of the patient will be determined after

opening the envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
Only the main researcher of the research is aware of the assignment of the codes, and until the end of the research, it will not be clear for the patient, the treating physician and those who evaluate the results, whether A or B is a placebo or the studied probiotic combination.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Saffarian Alley, Golshahr Blvd, Karaj

City

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Alborz

Postal code

3198764653

Approval date

2022-11-12, 1401/08/21

Ethics committee reference number

IR.ABZUMS.REC.1401.202

Health conditions studied

1

Description of health condition studied

Functional constipation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Treatment of functional constipation

Timepoint

The beginning of the study (before the start of the intervention), one week later, week 3, week 5, and week 7

Method of measurement

doctor checkup

2

Description

Abdominal pain

Timepoint

The beginning of the study (before the start of the intervention), one week later, week 3, week 5, and week 7

Method of measurement

doctor checkup

3

Description

Side effects

Timepoint

The beginning of the study (before the start of the intervention), one week later, week 3, week 5, and week 7

Method of measurement

doctor checkup

4

Description

Need for rescue treatment

Timepoint

The beginning of the study (before the start of the intervention), one week later, week 3, week 5, and week 7

Method of measurement

doctor checkup

Secondary outcomes

empty

Intervention groups

1

Description

Pidrolax drug (Pidrolax 4000 powder, 70g packets, made by Sepidaj Daru Company) is prescribed according to the following method: Children's dose 2 to 6 years old: 5 grams (one tablespoon) dissolved in a quarter of a glass of water or fruit juice and preferably eaten in the morning on an empty stomach. Children from 7 to 14 years old: 10 grams (one tablespoon) dissolved in half a glass of water or fruit juice and preferably eaten in the morning on an empty stomach. The patient should be repeated, and then in the following days, according to the patient's response status, the drug dose should be adjusted so that he has at least one soft stool per day. In case of no response despite taking the maximum dose of Pidrolax, the situation should be reported to the project manager. To take the necessary measures to correct the treatment. The main drug under investigation is the probiotic *Lactobacillus roteri* (RoteFlor powder, produced by Farabiotic Company) in the form of one-gram sachets containing 300 mg of lyophilized active cells (equivalent to 8×10^8 CFU), which according to the doctor's prescription, one sachet per day in half a glass of cold

liquid or yogurt. It is solved and consumed. In the first session, complete explanations about the treatment process, how to take medicines, diet, necessary behavioral training and danger signs are given to the parents, and the patient's information and history are recorded. After the start of the treatment, in the weeks 1st, 3rd, 5th and 7th, during a phone call or in person (according to the discretion of the patient's parents), the patient's condition is measured and the course of the symptoms is recorded, and the necessary corrections are applied in the way of implementing the treatment or any side issues that arise. The treatment is carried out for 7 weeks, and the parents are advised to avoid stopping or changing the medication without coordinating with the doctor. If the child has not had a stool for three consecutive days, life-saving treatment with liquid paraffin medicine with a dose of 1-3 cc /kg will be used.

Category

Treatment - Drugs

2

Description

Pidrolax drug (Pidrolax 4000 powder, 70g packets, made by Sepidaj Daru Company) is prescribed according to the following method: Children's dose 2 to 6 years old: 5 grams (one tablespoon) dissolved in a quarter of a glass of water or fruit juice and preferably eaten in the morning on an empty stomach. Children from 7 to 14 years old: 10 grams (one tablespoon) dissolved in half a glass of water or fruit juice and preferably eaten in the morning on an empty stomach. The patient should be repeated, and then in the following days, according to the patient's response status, the drug dose should be adjusted so that he has at least one soft stool per day. In case of no response despite taking the maximum dose of Pidrolax, the situation should be reported to the project manager. To take the necessary measures to correct the treatment. The control group will receive placebo which is similar to the main drug, a powder produced by Farabiotic Company in the form of one-gram sachets which according to the doctor's prescription, one sachet per day in half a glass of cold liquid or yogurt. It is solved and consumed. In the first session, complete explanations about the treatment process, how to take medicines, diet, necessary behavioral training and danger signs are given to the parents, and the patient's information and history are recorded. After the start of the treatment, in the weeks 1st, 3rd, 5th and 7th, during a phone call or in person (according to the discretion of the patient's parents), the patient's condition is measured and the course of the symptoms is recorded, and the necessary corrections are applied in the way of implementing the treatment or any side issues that arise. The treatment is carried out for 7 weeks, and the parents are advised to avoid stopping or changing the medication without coordinating with the doctor. If the child has not had a stool for three consecutive days, life-saving treatment with liquid paraffin medicine with a dose of 1-3 cc /kg will be used.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam ali medical education and treatment center

Full name of responsible person

Kumars Pourrostami

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Imam Ali Medical Education and Treatment Center,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Razieh Lotfi

Street address

Vice-Chancellor for Research and Technology,
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Karaj University of Medical Sciences

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

Razi Vaccine and Serum Research Institute

Full name of responsible person

Fereshteh Ansari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries

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Full name of responsible person

Kumars Pourrostami

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Specialist

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Person responsible for updating data

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Full name of responsible person

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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

All of the participants' individual data

When the data will become available and for how long

Access starts 6 months after results are published

To whom data/document is available

All researchers working in academic and scientific institutions and people working in the industry

Under which criteria data/document could be used

If a request with this theme is received, a decision will be made with the opinion of the research team.

From where data/document is obtainable

To the project manager, Dr. Kyomarth Pourrostami

What processes are involved for a request to access data/document

After submitting the request to the project manager, this request will be reviewed by a committee with the presence of all the people involved in the project, and then if the committee gives a positive answer, the data will be provided to the applicant.

Comments