Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Evaluating the Therapeutic Effectiveness of Probiotics on Pediatric Functional Constipation in a Cohort Aged 2 to 12 Years

Protocol summary

Study aim
An Examination of the Efficacy of Probiotics in Ameliorating Functional Constipation in Pediatric and Adolescent Populations

Design
Double-blind, randomized, placebo-controlled trial with 170 children, assessing probiotics' efficacy for functional constipation, using concealed, computerized randomization

Settings and conduct
Digestion; Among the patients of Bandar Abbas city; receiving lactulose with probiotics in the intervention group and lactulose with placebo in the control group; blinding of participants; Researchers and analysts

Participants/Inclusion and exclusion criteria
Demographic Age Group, Adherence to Rome IV Criteria, Related Recent Pharmacological Interventions, Surgical History Pertinent to Condition, Allergenic Reactions and Sensitivities, and Informed Consent for Study Participation

Intervention groups
Intervention Group: Participants in this group will receive probiotic treatment. The specific dosage of the probiotics is indicated on the medication packaging and is visible to the patients to ensure proper administration. The duration of the treatment, the frequency of administration, and any follow-up procedures are clearly defined and will be monitored throughout the study. Control Group: Participants in this group will receive a placebo, an inert substance designed to look and taste like the probiotic treatment but without the active probiotic ingredients. The placebo will be administered in the same manner and dosage as indicated on its packaging, mirroring the probiotics in the Intervention Group. This group acts as a baseline to compare the effects of the probiotics.

Main outcome variables
Functional constipation based on Rome IV criteria

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231004059611N1**
Registration date: **2024-01-08, 1402/10/18**
Registration timing: **prospective**

Last update: **2024-01-08, 1402/10/18**
Update count: **0**

Registration date
2024-01-08, 1402/10/18

Registrant information
Name
Samira Zakeri Shahvari
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 76 3366 7200
Email address
samirashahvari@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-20, 1402/10/30

Expected recruitment end date
2024-05-20, 1403/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluating the Therapeutic Effectiveness of Probiotics on Pediatric Functional Constipation in a Cohort Aged 2 to 12 Years

Public title
Probiotics in the Management of Functional Constipation in Children

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children aged 2 to 12 years Having functional constipation based on Rome criteria 4 Not using probiotics, prebiotics or antibiotics 4 weeks before the start of the research No history of gastrointestinal surgery Lack of sensitivity or tolerance to Lactobacillus roteri (Reuteflor) Interest in participating in the study and consent of family/guardian

Exclusion criteria:
Children with organic digestive disorders or any other underlying disease that can affect bowel function. Children with mental disability Current use of medications that affect bowel function such as laxatives or antidiarrheals History of using probiotics, prebiotics or antibiotics 4 weeks before the start of the research Inability or unwillingness to comply with the study protocol or follow-up History of participating in a different clinical trial in the last 3 months

Age
From **2 years** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **170**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization Unit: Individual participants. Method: Equal and independent chance of being assigned to either group, without age or characteristic stratification. Tool: Random allocation software for unbiased, random sequence generation. Sequence Generation: Pre-generated random sequence for assigning participants upon enrollment. Allocation Concealment: Hidden sequence from the research team to prevent selection bias. This approach ensures a fair and transparent allocation, maintaining the integrity and reliability of the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and Caregivers: Unaware of whether receiving probiotics or placebo. Researchers and Principal Investigator: Blind to treatment allocation to prevent bias in study management and interpretation. Healthcare Personnel (Physicians, Nurses, etc.): Not informed of individual treatments to ensure unbiased patient care. Data Collectors and Outcome Assessors: Kept blind to avoid influence on data recording or result interpretation. Data Safety and Monitoring Committee: Not Blinded Treatments, prepared by a third-party manufacturer, are coded and labeled indistinguishably. The manufacturer holds the treatment codes securely, only to be revealed after study completion or in medical emergencies. Participants are fully informed about their trial participation, but specific treatment details are withheld per double-blind study design, ensuring ethical conduct and study validity.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hormozgan University of Medical Sciences

Street address
Chamran Blvd

City
Bandar Abbas

Province
Hormozgan

Postal code
7916613885

Approval date
2023-08-04, 1402/05/13

Ethics committee reference number
IR.HUMS.REC.1402.220

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

Functional Constipation based on ROME IV Criteria

Timepoint

Initial Presentation and Subsequent Observations on Days 7, 14, 21, and 28, as well as Two Months Post-Administration of Probiotics

Method of measurement

ROME IV Criteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Reuteflor oral sachet, each Reuteflor sachet contains 800 million active lyophilized cells of Lactobacillus roteri (equivalent to 8*10^8 CFU), 1 to 2 sachets per day or according to the doctor's opinion, for use in children over two years of age and adolescents. and adults, the duration of use is 28 days, dissolve the contents of one sachet in a quantity of liquid or solid food compounds that are allowed by a doctor or pharmacist, such as water, yogurt or (cold) food and immediately Consume up to thirty minutes before. Make sure that the content of the sachet is well dissolved in the liquid, yogurt or food before consumption. Manufacturer: Faradaro Fan Avar Mehr Company (Farabiotic)

Category

Treatment - Drugs

2

Description

Control group: Receiving placebo, dosage, number of times of use, duration of use, method of use as in the intervention group. Manufacturer: Faradaro Fan Avar Mehr Company (Farabiotic)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bandar Abbas Children's Hospital

Full name of responsible person

Samira Zakeri Shahvari

Street address

Emam Khomeini Blvd., Daroupakhsh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Vali Alipour

Street address

Imam Hossein Blvd, Nabovat Town, Campus of Hormozgan University of Medical Sciences

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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

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Samira Zakeri Shahvari

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences

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Position
Associate Professor

Latest degree
Specialist

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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Position
medical scholar

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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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
Investigative Elements Comprising Individual Participant Data (IPD), Study Protocol, Statistical Analysis Blueprint, Informed Consent Documentation, Clinical Study Report, Analytical Coding Framework, and Data Categorization System. A portion of this data, specifically pertaining to the principal outcome, will be designated for scholarly sharing.

When the data will become available and for how long
Availability Period Commencing Approximately Six Months Subsequent to the Dissemination of the Final Published Article

To whom data/document is available
Investigators Affiliated with Academic and Scientific Institutions

Under which criteria data/document could be used
For the Purpose of Evaluating the Data Analysis Methodology, Execution of the Plan Utilizing Diverse Data Sets, Sampling Techniques, Randomization Processes, and Data Stratification, Alongside Assessment of the Exclusion Criteria for Disqualified Participants.

From where data/document is obtainable
Electronic Mail Contact Information of the Principal Project Coordinator: samirashahvari@gmail.com Bandar Abbas Children's Hospital and Hormozgan University of Medical Sciences

What processes are involved for a request to access data/document
Full Name and Surname Contact Information: Including Email Address and Mobile Number (where applicable) Academic Qualifications: Degree(s) Held Current Occupational Title and Position Field of Specialization: Specific Academic and Professional Focus Affiliated Organization: Name of the Institution or Entity Intended Purpose for Data Utilization Proposed Methodology for Data Interaction and Analysis

Comments