

# 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 anti-diarrheals 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  $8 \times 10^8$  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.

##### City

Bandar Abbas

##### Province

Hormozgan

##### Postal code

7915873665

##### Phone

+98 76 3366 6240

### Email

kdkh@hums.ac.ir

## 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

##### City

Bandar Abbas

##### Province

Hormozgan

##### Postal code

7919693116

##### Phone

+98 76 3371 0393

##### Email

research@hums.ac.ir

#### 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

##### Street address

Emam khomeyni Blvd, Daroupakhsh St.

##### City

Bandar Abbas

##### Province

Hormozgan  
**Postal code**  
7915873665  
**Phone**  
+98 76 3366 7200  
**Email**  
samirashahvari@gmail.com

## Person responsible for scientific 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  
**Street address**  
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**Postal code**  
7915873665  
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samirashahvari@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Bandare-abbas University of Medical Sciences  
**Full name of responsible person**  
Sobhan Montazerghaem  
**Position**  
medical scholar  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
General Practitioner  
**Street address**  
Jomhouri Eslami Blvd. ,Boostan St.  
**City**  
Bandar Abbas  
**Province**  
Hormozgan  
**Postal code**  
7919916663  
**Phone**

+98 76 3334 1460  
**Email**  
sobhan\_mono@yahoo.com

## 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