Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Probiotic Consumption on Improving the Quality of Life in Children Aged 6 to 13 Years with Cystic Fibrosis (CF)

Protocol summary

Study aim

Evaluation of the two-month effect of probiotic consumption on improving the quality of life of children aged 6–13 years with cystic fibrosis

Design

This study is a randomized, double-blind, parallel-group, phase 3 clinical trial conducted on 110 participants. Randomization was performed using the RAND function in Microsoft Excel.

Settings and conduct

a randomized double-blind clinical trial conducted at the CF Clinic of Tehran Children's Medical Center and Amir al-Momenin Hospital in Semnan. A total of 110 children aged 6–13 will be randomly assigned to two groups: the intervention group and control group. Quality of life will be measured using the CF-QoL questionnaire. participants and researchers will be blinded to group allocation

Participants/Inclusion and exclusion criteria

Inclusion Criteria:1)Definitive diagnosis of cystic fibrosis .2) Age between 6 and 13 years.3)Stable clinical condition 4) Ability to participate in the study and complete questionnaires.5)Informed consent . 6)No use of similar probiotics in the past month.Exclusion Criteria:1) Allergy or intolerance to probiotics. 2)Severe chronic or underlying diseases unrelated to CF. 3)Concurrent use of other probiotics or supplements. 4)Incomplete questionnaires or failure to attend follow-ups. 5)Acute infections or hospitalization during the study.

Intervention groups

Intervention group: Participants in this group will receive one sachet containing the probiotic Lactobacillus reuteri with a specified dose (1×10^8 CFU/day) daily for two consecutive months. Control (placebo) group: Participants in this group will also receive one sachet of a placebo daily for two months.

Main outcome variables

Improvement in quality of life will include evaluating the improvement of mood, appetite, weight gain, reduction of cough and wheezing, relief of abdominal pain, and the ability to tolerate daily and physical activities.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251004067497N1**
Registration date: **2025-10-08, 1404/07/16**
Registration timing: **prospective**

Last update: **2025-10-08, 1404/07/16**
Update count: **0**

Registration date

2025-10-08, 1404/07/16

Registrant information

Name

Mehri Ayati

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-18, 1404/07/26

Expected recruitment end date

2026-03-16, 1404/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Probiotic Consumption on Improving the Quality of Life in Children Aged 6 to 13 Years with Cystic Fibrosis (CF)

Public title

The Effect of Probiotics in Children with Cystic Fibrosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of cystic fibrosis (CF): The child or adolescent must have a CF diagnosis confirmed by a specialist physician, with medical documentation including pancreatic insufficiency and fecal elastase less than 200 µg/g Age between 6 and 13 years: Patients must fall within the study's age range to allow assessment of growth and physical functioning. Stable clinical condition: The child must be in a stable clinical state and must not have had an acute infection or hospitalization in the 4 weeks prior to the start of the study Ability to participate in the study and complete questionnaires: The patient or parents must be able to accurately respond to questionnaires regarding quality of life, respiratory, and gastrointestinal symptoms. Informed consent from parents or legal guardians: Participation in the study is only possible with written consent from the parents or legal guardian. No use of similar probiotics in the past month: Patients must not have used other probiotic supplements in the 4 weeks prior to the study to ensure the effect of the study probiotic is accurately assessed.

Exclusion criteria:

Allergy or intolerance to probiotics: Patients who are allergic to Lactobacillus reuteri or other components of the supplement, or who experience severe adverse effects from probiotic consumption, will be excluded from the study Severe chronic or underlying diseases unrelated to CF: Children who, in addition to CF, have severe chronic conditions (e.g., advanced heart, liver, or kidney failure) that could affect weight, appetite, or quality of life. Concurrent autoimmune diseases such as celiac disease or immunodeficiency disorders are also considered exclusion criteria Concurrent use of other probiotics or supplements: Patients who use other probiotics, similar nutritional supplements, or medications that directly affect gastrointestinal or respiratory symptoms of CF during the study. Incomplete questionnaires or lack of follow-up: Children who do not complete the questionnaires fully or fail to participate in regular follow-ups over the two-month study period. Acute infections or hospitalization during the study: Patients who are hospitalized or receive new inpatient treatments due to severe infections, as this could confound the effects of the probiotic.

Age

From **6 years** old to **13 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Method: Block Randomization (Randomization Block Method) In this method, participants are divided into blocks of four, and the order of assignment to the probiotic or placebo groups is determined randomly. This method ensures that the number of participants in each group is equal at the end of each block, maintaining balance between the groups. Unit of Randomization: Individual Randomization Each participant is independently and randomly assigned to one of the two groups (probiotic or placebo). Stratification: on similar age groups to maintain age homogeneity between the groups. Randomization Tool: Randomization List Generation of Random Sequence: The order of group assignments within each block of four participants was determined randomly. Allocation Concealment: The study was conducted as a double-blind trial (Double-blind)

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants were blinded to their assigned group (probiotic or placebo), and the sachets were coded and packaged by an independent person. The principal investigators did not have access to the actual content of the sachets to minimize bias in the conduct of the study and data collection. Outcome assessors and data analysts worked with coded data and were unaware of the actual group assignments. The independent person responsible for coding was not blinded and was in charge of preparing and labeling the sachets. The manuscript was prepared after data collection was completed and the codes were unblinded, and the person responsible had access to the actual group assignments; therefore, they were not blinded

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Semnan, Basij Boulevard, Head Office of Semnan University of Medical Sciences and Health Services

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Semnan

Province
Semnan

Postal code
99442-35147

Approval date
2025-09-22, 1404/06/31

Ethics committee reference number
IR.SEMUMS.REC.1404.176

Health conditions studied

1

Description of health condition studied
Cystic fibrosis in children aged 6 to 13 years

ICD-10 code
E84

ICD-10 code description
Cystic fibrosis

Primary outcomes

1

Description
Change in total quality of life score of patients with cystic fibrosis (CF) after two months of probiotic (Lactobacillus reuteri) consumption compared with placebo, based on the standardized Cystic Fibrosis Quality of Life Questionnaire (CF-QoL).This questionnaire assesses multiple domains including physical, psychological, and social aspects, as well as clinical symptoms such as daily activities, mood, appetite, respiratory symptoms (cough and wheezing), and gastrointestinal symptoms (abdominal pain).An increase in the questionnaire score indicates an improvement in the patient's quality of life. The total score will be compared before and after the intervention.

Timepoint
The effect of the probiotic is assessed two months after consumption. Patients' quality of life is measured before the start of the intervention and two months afterward.

Method of measurement
The Cystic Fibrosis Quality of Life Questionnaire (CF-QoL) translated by Talebi.
https://ispgh.ir/wp-content/uploads/2023/02/article6.pdf

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Children with cystic fibrosis (CF), aged 6 to 13 years, who will consume daily, for a period of two months, one sachet of a probiotic containing Lactobacillus reuteri (commercial name: Rutfloor), manufactured by Farabiotic Company, at a dose of $1X10^8$ CFU/day.

Category
Treatment - Drugs

2

Description
Control group: Children with CF in the same age range who will consume, daily for two months, a placebo sachet containing maltodextrin and 1% magnesium stearate, and free of any live bacteria, manufactured by Farabiotic Company.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran Children's Medical Center Clinic

Full name of responsible person
Dr.Mehri Ayati

Street address
Children's Medical Center, No. 62, next to Imam Khomeini Hospital, Dr. Mohammad Gharib Street, End of Keshavarz Boulevard, Tehran, Iran

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Recruitment center

Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Phone
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Email
rds@semums.ac.ir
Web page address
https://rtvc.semums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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
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Assistant Professor
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available