Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

comparing the effect of probiotics in improving pulmonary gastrointestinal symptoms with cystic fibrosis

Protocol summary

Study aim
The use of probiotics in improving pulmonary and gastrointestinal symptoms and growth in cystic fibrosis patients

Design
This study is a randomized, placebo-controlled, double-blind, single-center clinical trial on 108 patients.

Settings and conduct
The present study is a double-blind randomized controlled clinical trial and was conducted on a population of 6 to 12 years old with cystic fibrosis with pancreatic insufficiency who referred to the fibrosis clinic of the Children's Medical Center in 2003. The samples were randomly divided into two groups receiving probiotics and placebo. The researchers and patients were blinded to the content of the sachets. Patients in the probiotic group will receive Lactobacillus roteri (Rotflor) at the rate of 8/10 to the power of 8 units for one month, and the control group will receive a placebo. The results will be evaluated one month and three months after consuming one month of probiotics.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Cystic fibrosis patients with pancreatic insufficiency and aged between 6 and 12 years.
Exclusion criteria: concomitant diseases and contraindications for probiotic use.

Intervention groups
The intervention group includes cystic fibrosis patients who received the probiotic intervention The comparison group includes cystic fibrosis patients who received the placebo intervention

Main outcome variables
Fatty stool test Measuring the quality of life using a questionnaire Measuring the number of recent pulmonary exacerbation attacks in last year Throat culture Measurement of spirometry indicators

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240105060622N1**
Registration date: **2024-08-16, 1403/05/26**
Registration timing: **registered_while_recruiting**

Last update: **2024-08-16, 1403/05/26**
Update count: **0**

Registration date
2024-08-16, 1403/05/26

Registrant information
Name
MEHRI AYATI
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8841 5954
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-02-20, 1402/12/01
Expected recruitment end date
2024-09-21, 1403/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

comparing the effect of probiotics in improving pulmonary gastrointestinal symptoms with cystic fibrosis

Public title
comparing the effect of probiotics in cystic fibrosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
cystic fibrosis patient with an age range of 6 to 12 years Informed consent from parents Having pancreatic insufficiency Fecal elastase less than 200 micrograms per gram
Exclusion criteria:
having comorbidity disease except cystic fibrosis contraindication for probitotics
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **108**
Randomization (investigator's opinion)
Randomized
Randomization description
Among the patients visiting the Cystic Fibrosis Clinic of the Children's Medical Center, 108 patients between the ages of 6 and 12 will be randomized into two groups: probiotic (case) and placebo (control).Blocking was done individually and in blocks of 10 in the form of 5 cases and 5 controls, And in order to hide the direction of the block, they will be allocated to two groups of cases and controls using the https://www.sealedenvelope.com/ system with a ratio of 1:1.
Blinding (investigator's opinion)
Double blinded
Blinding description
Each Roteflor sachet contains 800 million active lyophilized cells of Lactobacillus roteri. Placebo is also made by Frabiotic similar to the main drug and provided to the researcher.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees, Research Ethics Committee of Children’s Medical Center- Tehran Universit
Street address
Children’s Medical Center, Gharib st, Keshavarz blv,
City
Tehran
Province
Tehran
Postal code
1419733151
Approval date
2023-10-19, 1402/07/27
Ethics committee reference number
IR.TUMS.CHMC.REC.1402.114

Health conditions studied

1

Description of health condition studied
Cystic Fibrosis
ICD-10 code
E84
ICD-10 code description
Cystic fibrosis

Primary outcomes

1

Description
fat stool
Timepoint
Measurement of fat excretion at the beginning of the study (before the start of the intervention), 30 and 90 days after starting one month of probiotic consumption.
Method of measurement
Paraclinic - laboratory-stool Exam

2

Description
Patient Weight
Timepoint
Measurement of the patient's weight at the beginning of the study (before the start of the intervention), 30 and 90 days after starting one month of probiotic consumption.
Method of measurement
scales

3

Description
quality of life
Timepoint
Measurement of the quality of life at the beginning of the study (before the start of the intervention), 30 and 90 days after starting one month of probiotic consumption.
Method of measurement

Questionnaire-Clinical File

4

Description
Forced Expiratory Volume in First Second (FEV1)
Timepoint
Measurement of the FEV1 at the beginning of the study (before the start of the intervention), 30 and 90 days after starting one month of probiotic consumption.
Method of measurement
Spirometry device

5

Description
Forced Vital Capacity (FVC)
Timepoint
Measurement of the FVC at the beginning of the study (before the start of the intervention), 30 and 90 days after starting one month of probiotic consumption.
Method of measurement
Spirometry device

6

Description
Throat culture
Timepoint
Measurement of the Throat culture at the beginning of the study (before the start of the intervention), 30 and 90 days after starting one month of probiotic consumption.
Method of measurement
Paraclinic - laboratory-Throat culture test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the probiotic group will receive Lactobacillus reuteri (Rotflor) at the rate of 10*8 CFU/d for one month.
Category
Treatment - Drugs

2

Description
Control group: Patients receive a placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Children’s Medical Center
Full name of responsible person
Parisa Rahmani
Street address
Children’s Medical Center, Gharib st, Keshavarz blv
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran 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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Mehri Ayati
Position
Pediatric Gastroenterology Fellowship
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address
Children's Medical Center Hospital, No. 62, next to Imam Khomeini Hospital, Dr. Mohammad Gharib St., Keshavarz Blvd.
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Person responsible for scientific inquiries

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Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Street address
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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Data can potentially be shared after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
The data will be available to researchers working in academic and scientific institutions and people working in industry
Under which criteria data/document could be used
Unlimited
From where data/document is obtainable
dr mehri ayati.09126148071.dr.m.ayati61@gmail.com
What processes are involved for a request to access data/document
First, a clear request should be given by official email, the reason for the data request should be stated and the work to be done to the end.
Comments