Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Lactobacillus Reuteri on pulmonary function in Cystic Fibrosis

Protocol summary

Study aim

The aim of this study is determining the effect of Lactobacillus Reuteri in Cystic Fibrosis patients on the pulmonary function, the frequency of pulmonary exacerbations, the frequency of hospitalizations, and anthropometric indices (height, weight, and BMI).

Design

Two arm parallel group randomized trial,triple blinded and phase 3 on 40 CF patients.

Settings and conduct

An informed consent form was obtained from parents/patients with CF who refer to Mofid Children's Hospital, after explaining the necessary information. Patients were divided into two groups randomly. A baseline spirometry test was performed from all patients. Demographic information and data related to the disease were obtained by a questionnaire. After measuring weight and height, BMI was calculated at baseline and after completion of the study. Frequency of pulmonary exacerbation, and hospitalization were recorded at baseline and 4 months later. Lactobacillus Reuteri supplement or placebo was prescribed to the patients daily for 4 months.

Participants/Inclusion and exclusion criteria

6-20 years old CF patients who come to Mofid's children Hospital with FEV1>40% are included in the study. The inclusion criteria are the ability to perform spirometry, no pulmonary exacerbation two weeks prior to study, and absence of any other chronic disease except those related to cystic fibrosis or its complications. Exclusion criteria: Patients who have been diagnosed with cystic fibrosis less than 6 months ago, occurrence of a new complication of cystic fibrosis during the past three months, and no routine follow up.

Intervention groups

Patients are randomly treated with lactobacillus reuteri sachet or placebo which is similar in color,shape and taste daily for 4 months.

Main outcome variables

Pulmonary function, FVC, FEV1. FEF25-75; pulmonary exacerbations; hospitalizations; weight; BMI; height

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181020041387N1**
Registration date: **2022-11-01, 1401/08/10**
Registration timing: **retrospective**

Last update: **2022-11-01, 1401/08/10**
Update count: **0**

Registration date

2022-11-01, 1401/08/10

Registrant information

Name

Seyedeh Zalfa Modarresi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3822 4000

Email address

zmodarres@farabi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-17, 1400/07/25

Expected recruitment end date

2022-02-09, 1400/11/20

Actual recruitment start date

2021-10-22, 1400/07/30

Actual recruitment end date

2022-02-19, 1400/11/30

Trial completion date
2022-08-16, 1401/05/25

Scientific title
The effect of Lactobacillus Reuteri on pulmonary function in Cystic Fibrosis

Public title
The effect of probiotics on CF

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who have been diagnosed with CF based on clinical signs and sweat Chloride test. No pulmonary exacerbation two weeks prior the study. Ability to perform spirometry test. The informed willingness to participate in the study. Presence of no other chronic disorder except complications related to CF Six to Twenty years old patients with Cystic Fibrosis disease. The Forced Expiratory Volume in 1 second (FEV1) greater than 40%. Stable clinical condition and no acute upper and lower respiratory infection.

Exclusion criteria:
Diagnosed as CF less than 6 months. New complication of CF during the past 3 months. No routine follow up. Disability to perform and repeat spirometry test according to American Thoracic Society criteria

Age
From **6 years** old to **20 years** old

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **40**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, patients are randomly divided into 2 groups: intervention group (as probiotic supplement group) and control group (as placebo group) (named groups A and B). Randomization is done by permuted block randomization method and concealment is done. Patients are divided into two groups using the above method. Six of the four combinations of intervention groups A and B are determined AABB ABAB ABBA BBAA BABA BAAB and randomly select each of the above combinations and those who agree to participate in the study are placed in study groups. It is also necessary to explain that in order to observe the concealment in the mentioned plan, the randomization operation is performed by a person other than the main researcher.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, the participant, the researcher doctor who provides the drug to the patient and is responsible for the follow-up of the patient, and the statistician, are blind to the groups. Medicines have two codes A or B. After the completion of the study and analysis by the statistician, the codes are determined by the manufacturing company.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research ethics committees of school of medicine-Shahid Beheshti University of Medical Sciences

Street address
Mofid's children hospital, Shariati street

City
Tehran

Province
Tehran

Postal code
1546815514

Approval date
2021-10-12, 1400/07/20

Ethics committee reference number
IR.SBMU.MSP.REC.1400.484

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
Pulmonary exacerbation frequency

Timepoint
During study period (4 months)

Method of measurement
Observing symptoms of exacerbation in follow-up visits or patient statements.

2

Description
Hospitalization frequency
Timepoint
During study period (4 months)
Method of measurement
Patient statements

3

Description
Weight Z-score
Timepoint
At baseline and at the end of study
Method of measurement
Scale

4

Description
Height Z-score
Timepoint
At baseline and at the end of study
Method of measurement
Meter

5

Description
BMI Z-score
Timepoint
At baseline and at the end of study
Method of measurement
Weight(kg)/ Height(m)2

6

Description
FEV1 Forced Expiratory Volume in First Second
Timepoint
At baseline and at the end of study
Method of measurement
Spirometry

7

Description
FEF25-75 Exhale middle airflow
Timepoint
At baseline and at the end of study
Method of measurement
Spirometry

8

Description
FEV1/FVC proportion of a person's vital capacity that they are able to expire in the first second of forced expiration to the full, forced vital capacity
Timepoint
At baseline and at the end of study
Method of measurement
Spirometry

9

Description
Forced Vital Capacity (FVC)
Timepoint
At baseline and at the end of study
Method of measurement
Spirometry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receiving standard treatment for cystic fibrosis plus one Lactobacilus reuterri sachet daily for 4 months.
Category
Treatment - Drugs

2

Description
Control group: Receiving standard treatment for cystic fibrosis plus one placebo sachet daily for 4 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofid's children Hospital
Full name of responsible person
Seyed Ahmad Tabatabaii
Street address
Shariati street
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Tehran
Province
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Postal code
1546815514
Phone
+98 21 2222 7021
Email
Ahmadtabatabaii@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person

Deputy of research and technology of Shahid Beheshti University of Medical Sciences

Street address
Daneshjou Blvd, District 1,

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Tehran

Province
Tehran

Postal code
1983969411

Phone
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info@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Seyedeh Zalfa Modaresi

Position
Fellowship

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

Street address
Mofid's children hospital, shariati street,

City
Tehran

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Postal code
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Phone
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Email
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Seyedeh Zalfa Modaresi

Position
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Other areas of specialty/work
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Person responsible for updating data

Contact

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Shahid Beheshti University of Medical Sciences

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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

Questionnaire information may be shared after completion of the study by removing the names and contact information of the patients.

When the data will become available and for how long

Twelve months

To whom data/document is available

Faculty members and students

Under which criteria data/document could be used

Request through email

From where data/document is obtainable

Email to dr.modarres@gmail.com

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

Email to dr.modarres@gmail.com

Comments