Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

The effectiveness of two types of probiotics (lactobacillusRhamnosus and Lactobacillus Reuteri) on the pulmonary function test of moderate asthmatic patients aged 10 – 18 years.

Protocol summary

Study aim

Determination and between-groups comparison of the mean FEV1, FVC, FEV1 / FVC, PEF, IL13, blood eosinophil percentage, and mean baseline asthma test (pre-test) • Determination and between-groups comparison of the mean FEV1, FVC, and other variables at post-test. • Determination and within-group comparison of the mean FEV1, FVC, and other variables in the study groups.

Design

Randomized clinical trial with control group, single-blind and parallel groups, phase 3 with 120 patients

Settings and conduct

120 eligible patients who will be referred to Shahid Mofteh Yasuj Children's Clinic will be examined. In the baseline, the dependent variables will be examined in the study groups and, after the intervention, the outcome variables will be measured again and compared in the groups.

Participants/Inclusion and exclusion criteria

Patients aged 10 - 18 years A well-known case of persistent moderate asthma All patients are taking fluticasone spray. No history of other respiratory illnesses Exclusion : • Immigration or death • Dissatisfaction with continuing the treatment. • In case of other infectious or chronic diseases during the research

Intervention groups

Intervention group 1. Lactobacillus Rhamnosus will be given 10 drops of this probiotic. Intervention group 2. Lactobacillus Ruteri 5 drops will be given daily and orally. Intervention group 3. The combined group will be given 10 drops of Lactobacillus Rhamnosus along with 5 drops of Lactobacillus Ruteri orally. Control group: For the control group, in the same color and similar glasses containing distilled water and orange essential oil, 10 and 5 drops will be given orally and daily.

Main outcome variables

Reduce asthma attacks, improving spirometry parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220329054368N1**
Registration date: **2022-05-21, 1401/02/31**
Registration timing: **prospective**

Last update: **2022-05-21, 1401/02/31**
Update count: **0**

Registration date

2022-05-21, 1401/02/31

Registrant information

Name

Farnaz sadat Javanmardi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3229 8671

Email address

farnaz.javanmardi@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of two types of probiotics (lactobacillusRhamnosus and Lactobacillus Reuteri) on the pulmonary function test of moderate asthmatic patients aged 10 – 18 years.

Public title

The effectiveness of probiotics on asthmatic patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between 10 - 18 years A well-known case of persistent moderate asthma that has just been diagnosed and, has a medical record and approval from an asthma and allergy specialist. All patients are taking fluticasone spray. Have no history of other respiratory illnesses including interstitial pneumonia, cystic fibrosis, sickle cell disease, and primary ciliary dyskinesia

Exclusion criteria:

Immigration or death of the patient. Patient dissatisfaction in continuing the treatment. In case of other infectious or chronic diseases during the research period.

Age

From **10 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done in a random block method. The size of the blocks is chosen randomly (for example, blocks 4, 8, and 12) in which there is an equal number of each group in each block.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are unaware of their group and medications (drugs or placebo).

Placebo

Used

Assignment

Parallel

Other design features

According to our knowledge, the present study is the first clinical trial study in Iran on the effect of probiotics in asthmatic patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of Medical Science

Street address

Eram Street, Alley NO.8

City

Shiraz

Province

Fars

Postal code

7143838466

Approval date

2022-03-30, 1401/01/10

Ethics committee reference number

IR.YUMS.REC.1400.038

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45.3

ICD-10 code description

Mild persistent asthma

Primary outcomes

1

Description

Degree of asthma control, interleukin 13, blood eosinophil percentage, forced expiratory volume, peak expiratory flow, forced vital capacity

Timepoint

At the beginning of the study and two months after the intervention.

Method of measurement

Asthma control test(ACT), spirometry, CBC diff, IL13 human kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Lactobacillus rhamnosus probiotic group. The amount of 10 drops of this probiotic will be

given daily and orally with the dropper.

Category

Treatment - Drugs

2

Description

Intervention group 2: Lactobacillus Rutri probiotic group. 5 drops will be given daily and orally.

Category

Treatment - Drugs

3

Description

Intervention group 3: Combination of Lactobacillus Rhamnosus and Lactobacillus Ruteri.10 drops of Lactobacillus Rhamnosus with 5 drops of Lactobacillus Ruteri will be given orally.

Category

Treatment - Drugs

4

Description

Control group: Placebo group.In glasses of the same color and similar to Lactobacillus Rhamnosus containing distilled water and orange essential oil, 10 drops will be given orally and daily.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mofteh Yasuj Children's Clinic

Full name of responsible person

Dr. Ali Fazel

Street address

Golestan NO.15, Pasdaran street.

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

0743323515

Phone

+98 74 1222 3299

Fax

+98 74 3323 5153

Email

farnaz.javanmardi@yums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Dr. Amir Ghanbari

Street address

School of Medicine, Campus of University of Medical Sciences, Next to Imam Sajjad Hospital, Shahid Dr. Ghorban Ali Jalil St

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

0743323515

Phone

+98 74 3323 0290

Email

farnaz.javanmardi@yums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Faradaru company

Proportion provided by this source

50

Public or private sector

Private

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

Yasouj University of Medical Sciences

Full name of responsible person

Farnaz Sadat Javanmardi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Alley No. 8, Eram street

City

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Farnaz Sadat Javanmardi

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Resident

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farnaz.javanmardi@yums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Farnaz sadat Javanmardi

Position
Resident

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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
Only data can be shared without patient names.

When the data will become available and for how long
6 months after the publication of the article.

To whom data/document is available
Researchers

Under which criteria data/document could be used
Sharing results to improve children's health.

From where data/document is obtainable
FarnazSadat Javanmardi

What processes are involved for a request to access data/document
Formal request to be sent via email.

Comments