

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

The effect of Probiotics on control of clinical features and exacerbation of Bronchiectasis

Protocol summary

Summary

In this randomized double-blinded case-control clinical trial study, 60 patients with Bronchiectasis who referred to Pulmonary Subspecialty Clinic of Razi Hospital from March 2017 to March 2018 will be enrolled. The patients will be male or females above 18 years old who fulfilled the inclusion and exclusion criteria of the study. After obtaining an informed consent from the subjects, they will be randomly categorized in either the intervention (group A) or the control group (group B). At the beginning of the trial, study variables including the patients' demographic features (age, weight, height) will be recorded. Also, a sputum culture will be obtained and a primary spirometry will be performed. Furthermore, histories of exacerbations of the disease in the same time-period in the last two years will be asked and recorded. To perform the study, the patients in both groups will be treated for their underlying disease, with the intervention group taking additional Lactocare probiotic. This joint formula contains high amounts of seven "helpful" bacterial species, including Lactobacillus rhamnosus, Bifidobacterium longum, Bifidobacterium breve, Lactobacillus bulgaricus, Lactobacillus casei, Lactobacillus acidophilus, Streptococcus thermophilus, together with Fructooligosaccharides probiotic in forms of capsules. These capsules and their placebos are prescribed twice a day for six months. The patients will be visited in the same clinic every month and their clinical manifestations and possible exacerbations will be recorded. At the end of the six-month period, the results of sputum cultures and patients' weight will be evaluated and a second spirometry will be performed. These clinical findings will also be compared with the same time period of last year by asking the patients about them. Finally, the data will be compared and analyzed

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041514085N4**

Registration date: **2017-08-01, 1396/05/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-01, 1396/05/10

Registrant information

Name

Ali Alavi

Name of organization / entity

Inflammatory Lung Disease Research Center, Razi Hospital, Gilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3354 2460

Email address

ali_alavi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

1-Vice Chancellor of Research, Guilan University of Medical Sciences
2-Tehran Zist Takhmir Company

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Probiotics on control of clinical features and exacerbation of Bronchiectasis		2017-02-25, 1395/12/07
Public title The effect of Probiotics on control of clinical features of Bronchiectasis		Ethics committee reference number IR.GUMS.REC.1395.360
Purpose Treatment		Health conditions studied
Inclusion/Exclusion criteria Inclusion criteria: More than 18 years, Not being Pregnant; Exclusion criteria: Cardiovascular diseases; Diabetes; Use of immunosuppressive agents; Bronchiectasis due to foreign body or tumor; Disable to do spirometry		1 Description of health condition studied bronchiectasis ICD-10 code j47 ICD-10 code description Bronchiectasis
Age From 18 years old		Primary outcomes
Gender Both		1 Description severity of cough Timepoint The same 6 month of last year and at during of intervention Method of measurement by asking the person
Phase 2-3		2 Description amount of sputum Timepoint The same 6 month of last year and before of intervention and end of sixth months Method of measurement by asking the person
Groups that have been masked <i>No information</i>		3 Description severity of dyspnea Timepoint The same 6 month of last year and at during of intervention Method of measurement by asking the person base on MRC scale
Sample size Target sample size: 60		4 Description results of sputum culture Timepoint before of intervention and end of sixth month Method of measurement smear and anti biogram
Randomization (investigator's opinion) Randomized		5 Description FEV1, FVC, FEV1/FVC Timepoint before of intervention and end of sixth month
Randomization description		
Blinding (investigator's opinion) Double blinded		
Blinding description		
Placebo Used		
Assignment Parallel		
Other design features After obtaining an informed consent from the subjects, they will be randomly categorized in either the control group (group A) or the placebo group (group B). In this way, the number will be assigned randomly to the patients who enter the study. This number identifies a person in one group (A is control group and B is placebo group)		
Secondary Ids empty		
Ethics committees		
1 Ethics committee Name of ethics committee Research Council of Guilan University of Medical Sciences Street address Vice Chancellor of Research of Guilan University of Medical Sciences, Gaz Avenue City Rasht Postal code Approval date		

Method of measurement

spirometry

6

Description

body mass index

Timepoint

before of intervention and end of sixth month

Method of measurement

weight over square of height

Secondary outcomes

1

Description

need of prophylactic antibiotic for disease exacerbation

Timepoint

during of intervention

Method of measurement

by asking the person

2

Description

rate of hospitalizations

Timepoint

during of intervention

Method of measurement

by asking the person

3

Description

rate of exacerbation of disease

Timepoint

during of intervention

Method of measurement

by asking the person

Intervention groups

1

Description

Intervention group 1(intervention group)will received routine drugs for treatment, they will treated with lactocare for 6 months

Category

Treatment - Drugs

2

Description

Intervention group 2 (control group) will received routine drugs for treatment and placebo during 6 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital; Pulmonary Subspeciality Clinic

Full name of responsible person

Dr Ali Alavi

Street address

Razi Hospital; Pulmonary Subspeciality Clinic

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research of Guilan University of Medical Sciences

Full name of responsible person

Dr Shadman Nemati

Street address

Vice Chancellor of Research of Guilan University of Medical Sciences ; Gaz Avenue

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor of Research of Guilan University of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Zist Takhmir Tehran

Full name of responsible person

Mrs Tajic

Street address

Number597, Heydarkhani Avenue, Farjam Street, Resalat Avenue

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zist Takhmir Tehran

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Inflammatory Lung Disease Research Center

Full name of responsible person

Dr Shabnam Ziapour

Position

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Other areas of specialty/work

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty