Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 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 berve, 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
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ali_alavi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

1-Vice Chancellor of Research,Guilan University of Medical Sciences2-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

Public title
The effect of Probiotics on control of clinical features of Bronchiectasis
Purpose
Treatment
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
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
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
2017-02-25, 1395/12/07
Ethics committee reference number
IR.GUMS.REC.1395.360

Health conditions studied

1

Description of health condition studied
bronchiectasis
ICD-10 code
j47
ICD-10 code description
Bronchiectasis

Primary outcomes

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

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

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

4

Description
results of sputum culture
Timepoint
before of intervention and end of sixth month
Method of measurement
smear and anti biogram

5

Description
FEV1, FVC, FEV1/FVC
Timepoint
before of intervention and end of sixth month

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 Chancellar of Research of Guilan University of Medical Sciences
Full name of responsible person
Dr Shadman Nemati
Street address
Vice Chancellar 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 Chancellar 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
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Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
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Person responsible for updating data

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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