Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparative study of the effect of levofloxacin with azithromycin in improving pulmonary function in patients with exacerbated bronchiectasis, a double-blind clinical trial

Protocol summary

Study aim

Comparative study of the effect of levofloxacin with azithromycin in improving pulmonary function in patients with exacerbated bronchiectasis

Design

This double blind clinical trial is performed on 72 patients with exacerbated bronchiectasis that randomly divided into two equal groups In parallel. Block randomization method will be used for random allocation. The blocks size will be 4 and for this purpose; 23 blocks with 4 subjects in each block will be used. For selecting each blocks; statistical software and the block number will be selected.

Settings and conduct

This study was conducted as a clinical trial study with 72 patients who referred to lung ward of Imam Hossain Hospital of Shahroud. In this study the evaluator and analyzer are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with definite diagnosis of aggravated non-fibrocystic bronchiectasis disease; Not having moderate to severe heart failure (EF>50); Stable vital signs; Having a controlled and stable drug regimen during the study. Exclusion criteria: Gastrointestinal problems such as severe nausea and vomiting; various cancers of the respiratory system; chronic kidney and liver disease at the same time; History of any surgery on the respiratory system at least in the last year; A history of receiving any antibiotics and corticosteroid drugs in the last month; and pregnancy and breastfeeding.

Intervention groups

In intervention group, routine treatment + levofloxacin tablets 250 mg twice a day for two weeks and then 250 mg once a day for four weeks (6 weeks in total) will be prescribed. For patients in the control group, routine treatment + azithromycin tablets 250 mg twice a day for two weeks and then 250 mg once a day for four weeks (6 weeks in total) will be prescribed.

Main outcome variables

Measuring oxygen saturation (o2sat) and measurement of lung volumes and capacities.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100102002954N28**
Registration date: **2022-09-01, 1401/06/10**
Registration timing: **prospective**

Last update: **2022-09-01, 1401/06/10**
Update count: **0**

Registration date

2022-09-01, 1401/06/10

Registrant information

Name

Mohammad Bagher Sohrabi

Name of organization / entity

Shahroud University of Medical Ssciences and Health

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

mb.sohrabi@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-11-11, 1401/08/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effect of levofloxacin with azithromycin in improving pulmonary function in patients with exacerbated bronchiectasis, a double-blind clinical trial

Public title
Comparing the effect of levofloxacin with azithromycin in improving pulmonary function of patients with bronchiectasis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with definite diagnosis of aggravated non-fibrocystic bronchiectasis disease; Not having moderate to severe heart failure (EF>50); Stable vital signs; Having a controlled and stable drug regimen (according to the opinion of a pulmonologist) during the study; Informed consent to participate in research.
Exclusion criteria:
Gastrointestinal problems such as severe nausea and vomiting; The presence of various cancers of the respiratory system; The presence of chronic kidney and liver disease at the same time; History of any surgery on the respiratory system at least in the last year; A history of receiving any antibiotics in the last month; A history of receiving any corticosteroid drugs in the past month; Pregnancy and breastfeeding.
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: use block. Random unit: individual. Randomization tool: An online randomization website. Sequence building: using block randomization method with block size of 4. Concealing method: using closed and opaque envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, clinical evaluator and analyzer are blinded. The allocation of patients into two groups A and B is done by a qualified nurse who has no aware of the actions performed in the two groups. Clinical examination and outcome evaluation will be record by a qualified nurse without any information about the type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahroud University of Medical Sciences
Street address
Shahroud University of Medical Sciences; 7 Tir squer; Shahroud
City
Shahroud
Province
Semnan
Postal code
3616647555
Approval date
2022-07-30, 1401/05/08
Ethics committee reference number
IR.SHMU.REC.1401.126

Health conditions studied

1

Description of health condition studied
Bronchiectasis
ICD-10 code
J47.1
ICD-10 code description
Bronchiectasis with (acute) exacerbation

Primary outcomes

1

Description
Measuring oxygen saturation (o2sat)
Timepoint
Once every two weeks
Method of measurement
Standard method with pulse oximetry device

2

Description
Measurement of lung volumes and capacities
Timepoint

Once every two weeks

Method of measurement

Standard method with spirometer

Secondary outcomes

1

Description

Measuring discomfort from breathing (Dyspnea)

Timepoint

Once every two weeks

Method of measurement

Using standard Borg questionnaire

2

Description

Measurement of white blood cells

Timepoint

Once every two weeks

Method of measurement

By standard laboratory method

Intervention groups

1

Description

Intervention group: For patients in the intervention group, after justifying the patients and providing the necessary training, routine treatment includes: use of oxygen, bronchodilators, expectorant drugs + levofloxacin tablets 250 mg twice a day for two weeks and then 250 mg once a day for four weeks (6 weeks in total) will be prescribed.

Category

Treatment - Drugs

2

Description

Control group: For patients in the control group, after justifying the patients and providing the necessary training, routine treatment will include: use of oxygen, bronchodilators, expectorant drugs + azithromycin tablets 250 mg twice a day for two weeks and then 250 mg once a day for four weeks (6 weeks in total) will be prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital of Shahroud

Full name of responsible person

Dr. Maryam Hagimirghasemi

Street address

Imam Hossein Hospital., End Imam street., Shahroud; Iran

City

Shahroud

Province

Semnan

Postal code

3616611151

Phone

+98 23 3234 2000

Fax

+98 23 3233 3902

Email

drhagimirghasemi@shmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hasan Imamian

Street address

Vice chancellor for research; Shahroud University medical Sciences; 7th Tir squar; Shahroud

City

Shahroud

Province

Semnan

Postal code

3616647555

Phone

+98 23 3239 4499

Fax

+98 23 3239 4800

Email

pajouhesh@shmu.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Vice chancellor for research; Shahroud University medical and 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
Shahroud University of Medical Sciences
Full name of responsible person
Dr. Bibimahsa Forghani
Position
Resident of Internal Medicine
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
Imam Hossein Hospital., End Imam street., Shahroud., Iran
City
Shahroud
Province
Semnan
Postal code
3616611151
Phone
+98 23 3234 2000
Fax
+98 23 3233 3902
Email
daaroo85@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Dr. Maryam Hagimirghasemi
Position
Pulmonologist
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Imam Hossein hospital., End Imam street., Shahroud., Iran
City
Shahroud
Province
Semnan
Postal code
3616611151
Phone
+98 23 3234 2000
Fax
+98 23 3233 3902
Email
drhagimirghasemi@shmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Dr. Mohammad Bagher Sohrabi
Position
General Practitioner
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Imam Hossein Hospital., End Imam street., Shahroud., Iran
City
Shahroud
Province
Semnan
Postal code
3616611151
Phone
+98 23 3234 2000
Fax
+98 23 3233 3902
Email
mb.sohrabi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available