

# 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 Sciences 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