

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The preventive effects of short-course treatment with Levofloxacin in comparison with Azithromycin in bronchiectasis patients

Protocol summary

Study aim

Determination and comparison of the effect of short-term treatment with Levofloxacin and Azithromycin in bronchiectasis patients in the prevention of respiratory tract infections

Design

This is a randomized, double-blind, parallel-based and community-based clinical trial study conducted in Phase 3 on 82 patients with bronchiectasis diagnosis. Patients randomly divided into two groups receiving Azithromycin or Levofloxacin on basis of random numbers.

Settings and conduct

After approving the research proposal from medical school, the researcher will enter the patients who have criteria for entering the study after explaining the goals and conditions of the study and obtaining informed consent. In one group, Levofloxacin will receive 5 days a month, and in another group, patients will receive Azithromycin at a dose of 250 mg per day throughout the duration of study. Medications will be identified with codes A and B and will be in the same shape, and therefore the patient and assessing person (physician) will not know how patients allocated.

Participants/Inclusion and exclusion criteria

All patients with generalized bronchiectasis accompanied by septic mucus that have exacerbated disease more than 3 times in year
Entry criteria: having a definite diagnosis of bronchiectasis, satisfaction to participate in study
Exit criteria: having CF, allergies, asthma, tuberculosis

Intervention groups

Patients will be randomly divided into two equal groups after entering the study. In one group, Levofloxacin 500 mg will receive 5 days in month, and in another group, patients will receive Azithromycin 250 mg per day throughout the duration of study. Patients have been followed for one year and during this time, the number of admissions and number of exacerbations will be compared.

Main outcome variables

Average frequency of exacerbations of bronchiectasis, average admission rate, frequency of side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190109042312N1**

Registration date: **2019-02-19, 1397/11/30**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-19, 1397/11/30**

Update count: **0**

Registration date

2019-02-19, 1397/11/30

Registrant information

Name

Farzane Peykfallak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5789

Email address

farzane_p471@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-19, 1397/11/30

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The preventive effects of short-course treatment with Levofloxacin in comparison with Azithromycin in bronchiectasis patients

Public title
Effect of Levofloxacin and Azithromycin in bronchiectasis patients treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Having a definitive diagnosis of bronchiectasis
 Satisfaction to participate in the study
Exclusion criteria:
 Having cystic fibrosis, allergies, asthma, tuberculosis

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **82**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients randomly divided into two groups receiving Azithromycin or Levofloxacin on the basis of random numbers. Medications will be marked with codes A and B and will be in the same shape.

Blinding (investigator's opinion)
Double blinded

Blinding description
Medications will be identified with codes A and B and will be in the same shape, and therefore the patient and the assessing person (physician) will not know how patients allocated.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address
Zahedan University of Medical Sciences, Dr Hesabi sq., Zahedan, Iran

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2019-02-03, 1397/11/14

Ethics committee reference number
IR.ZAUMS.REC.1397.429

Health conditions studied

1

Description of health condition studied

Bronchiectasis

ICD-10 code

J47

ICD-10 code description

Bronchiectasis

Primary outcomes

1

Description

exacerbation

Timepoint

During and after the end of the data collection

Method of measurement

By the form of information

Secondary outcomes

1

Description

Number of admissions

Timepoint

During and after the end of the data collection

Method of measurement

By the form of information

Intervention groups

1

Description

Intervention group: Levofloxacin - In this group, patients will receive Levofloxacin for 5 days with the dose of 500mg in a month and will be followed for one year, during that time the number of admissions and the number of exacerbations will be examined and compared.

Category

Treatment - Drugs

2

Description

Intervention group: Azithromycin - In this group, patients will receive Azithromycin at a dose of 250 mg per day throughout the study period and will be followed for one year, during that time the number of admissions and the number of exacerbations will be examined and compared.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ibn Abitaleb Hospital of Zahedan

Full name of responsible person

Dr Kazem Momeni

Street address

Khalije Fars highway, Salamat blvd., Ali ibn Abitaleb Hospital of Zahedan

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drkazemmomeni@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Mohsen Taheri

Street address

Zahedan University of Medical Sciences, Dr Hesabi sq., Zahedan, Iran

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Email

taheri@zaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Zahedan University of Medical 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

Zahedan University of Medical Sciences

Full name of responsible person

Farzane Peykfallak

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Zahedan University of Medical Sciences, Dr Hesabi sq., Zahedan, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Only part of the data, such as information on the main outcome, can be shared.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Data will only be available to academic researchers

Under which criteria data/document could be used

It is only allowed to use the data to give ideas for future research

From where data/document is obtainable

Access to the documentation will be possible through the University's Research deputy

What processes are involved for a request to access data/document

Access to the documentation will be possible by following the relevant routine

Comments