Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Effects of Adding Azithromycin to Standard Outpatient and Inpatient COPD Treatment in Shahrekord University of Medical Sciences Hospitals

Protocol summary

Study aim

Determining the effectiveness of azithromycin treatment protocol and standard treatment in comparison with standard treatment alone in patients with chronic obstructive pulmonary disease (COPD)

Design

A controlled, double-blind, placebo, randomized controlled clinical trial is performed on 100 patients. For randomization, the blocking method (quadruple blocks) will be used.

Settings and conduct

Two-blind study. Patients are first subjected to initial pulmonary examinations to determine the initial values of functional tests. Then, until random allocation, they are placed in the intervention and control groups, and spirometric indices and the rate of improvement and control of the disease are recorded using CAT and MMRC questionnaires.

Participants/Inclusion and exclusion criteria

Inclusion criteria Diagnosis of COPD by an internal medicine specialist, hospitalization based on the global pioneers of chronic obstructive pulmonary disease (GOLD), stable physical and mental condition of the patient, age 40-70 years, no other chronic diseases such as disease Of orthopedics and locomotion, multiple sclerosis and cancer. Exclusion criteria Lack of motivation for the patient to continue cooperation, immune system deficiency (recurrent respiratory infections and worsening of shortness of breath), pneumonia, embolism. Kidney failure, hearing loss Existence of concomitant asthma Complications of azithromycin Existence of atopy or allergic rhinitis Cancer Serious non-pulmonary disease Liver dysfunction, cholestatic jaundice, infiltration and cosolidation on chest x-ray Patients with acute exacerbation of COOD are also excluded from the study.

Intervention groups

Intervention group: Oral azithromycin and standard treatment. Control group: receiving standard treatment alone.

Main outcome variables

Spirometric parameters; evaluation of recovery and control of COPD using CAT and MMRC questionnaires.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210405050849N1**
Registration date: **2021-05-28, 1400/03/07**
Registration timing: **prospective**

Last update: **2021-05-28, 1400/03/07**
Update count: **0**

Registration date

2021-05-28, 1400/03/07

Registrant information

Name

Ebrahim Abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 0016

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of Adding Azithromycin to Standard Outpatient and Inpatient COPD Treatment in Shahrekord University of Medical Sciences Hospitals

Public title
Evaluation of the effect of oral azithromycin on COPD patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of COPD by an internal medicine physician, based on the classification of global pioneers of chronic obstructive pulmonary disease (GOLD) No other chronic diseases such as orthopedic and motor diseases, multiple sclerosis or cancer. hospitalization stability of the patient's physical and mental condition
Exclusion criteria:
Lack of motivation of the patient to cooperation Immune system defects (recurrent respiratory infections and worsening of shortness of breath) Existence of concomitant asthma Complications of azithromycin non-pulmonary diseases like cancer; liver dysfunction, cholestatic jaundice, Infiltration and consolidation in chest x-ray Patients with acute exacerbation of COPD Existence of atopy or allergic rhinitis pneumonia embolism Kidney failure hearing loss
Age
From **40 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done using the block method by a person who is not related to the study. Randomization of serial numbers of drug packages and placebo is done by a person who is not involved in the project and using a randomization table. The number of each package corresponds to the number of study patients.
Blinding (investigator's opinion)
Double blinded
Blinding description
The two-way study is blind. Outcome assessors and participants are unaware of the type of grouping (intervention or placebo) (double-blind). Packages containing the drug and placebo are quite similar in shape and color.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences
Street address
Parastar Aven.Hajar Hospital
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8816754633
Approval date
2020-06-30, 1399/04/10
Ethics committee reference number
IR.SKUMS.REC.1399.109

Health conditions studied

1

Description of health condition studied
Chronic Obstructive Pulmonary Disease
ICD-10 code
J44.9
ICD-10 code description
Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description
FEV1/ FVC
Timepoint
Two months after starting the study
Method of measurement
Spirometry

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients in the control group receive conventional therapy (triple therapy) and placebo. Triple therapy includes inhaled anticholinergics (long-acting, short-acting), inhaled bronchodilators (long-acting, short-acting), ICS ± oral corticosteroids (for two weeks).

Category
Treatment - Drugs

2

Description
Intervention group: In this group, in addition to triple therapy, patients are treated with oral azithromycin 250 mg daily made by Tehran Shimi Company for 2 months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hajar Hospital, Shahrekord

Full name of responsible person
Akbar Soleimani

Street address
Parastar Aven

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st-abbasi.e@skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Mehraban Sadeghy

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Grant name

Grant code / Reference number

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

Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
Ebrahim Abbasi Monjezi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document
Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long
2021-2022

To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used
I have not decided yet

From where data/document is obtainable
I have not decided yet

What processes are involved for a request to access data/document
I have not decided yet

Comments