

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 consolidation 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

Email address

st-abbasi.e@skums.ac.ir

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

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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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Contact

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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