

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The effect of azithromycin on the prevention of asthma attack in patients with chronic asthma, a clinical trial

Protocol summary

Study aim

Determining the effect of azithromycin on the prevention of asthma attack in patients with chronic asthma

Design

This is a parallel randomized controlled clinical trial that will be performed on 116 patients with chronic asthma. Randomization in this research is done using quadri blocks using syntax written in SPSS program.

Settings and conduct

This study will conduct as a clinical trial study with 116 patients who will refer to Imam Hossain Hospital of Shahroud. Patients must sign an informed consent form before entering the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with a diagnosis of chronic asthma by spirometric and clinical findings; chronic asthma for at least the last six months; do not take any antibiotics for at least the last month and conscious consent to participate in research. Exclusion criteria: incidence of any severe asthma attack during the study period; hypersensitivity to azithromycin or intolerance during treatment; existence of infectious and severe respiratory diseases in at least one month; history of any surgery on the respiratory tract and existence of severe heart disease that has led to severe respiratory problems.

Intervention groups

For patients in the intervention group, in addition to routine treatments involving the use of inhaled sprays (airway dilators and corticosteroids), azithromycin 250 mg capsules twice daily for the first day and then daily for four days. The next is given and from the second week to the twelfth week, three capsules (one day in between) of the capsule are prescribed and for patients in the control group, only routine treatments involving the use of inhaled sprays (airway dilators and corticosteroids) will be prescribed for 12 weeks.

Main outcome variables

Measuring the severity of chronic asthma and Maximum

expiratory volume in the first second (FEV1).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100102002954N24**

Registration date: **2021-06-13, 1400/03/23**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-13, 1400/03/23**

Update count: **0**

Registration date

2021-06-13, 1400/03/23

Registrant information

Name

Mohammad Bagher Sohrabi

Name of organization / entity

Shahroud University of Medical Sciences and Health

Country

Iran (Islamic Republic of)

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+98 23 3239 5054

Email address

mb.sohrabi@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-31, 1400/03/10

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of azithromycin on the prevention of asthma attack in patients with chronic asthma, a clinical trial

Public title

The effect of azithromycin on the prevention of asthma attacks

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with a diagnosis of chronic asthma by spirometric and clinical findings, Chronic asthma for at least the last six months, Do not take any antibiotics for at least the last month, Conscious consent to participate in research.

Exclusion criteria:

Incidence of any severe asthma attack during the study period, Hypersensitivity to azithromycin or intolerance during treatment, Existence of infectious and severe respiratory diseases in at least one month, History of any surgery on the respiratory tract, Existence of severe heart disease that has led to severe respiratory problems.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were allocated to intervention and control groups according to random allocation table that illustrated by a statistician. Randomization was done using permuted block randomization method (Block size was 4) using blocked random allocation syntax in SPSS software. For calculation sample size was 116 and number of blocks was 29. Allocation concealment was done using closed opaque envelope.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences; 7 Tir squer, Shahroud

City

Shahroud

Province

Semnan

Postal code

3616611151

Approval date

2019-08-17, 1398/05/26

Ethics committee reference number

IR.SHMU.REC.1398.054

Health conditions studied

1

Description of health condition studied

Chronic Asthma

ICD-10 code

J45.5

ICD-10 code description

Severe persistent asthma

Primary outcomes

1

Description

Measuring the severity of chronic asthma

Timepoint

Once a month

Method of measurement

ACQ standard questionnaire

2

Description

Maximum expiratory volume per the first second (FEV1)

Timepoint

Once a month

Method of measurement

Micromedical spirometer

Secondary outcomes

1

Description

Measurement of expiratory nitric oxide ratio

Timepoint

Once a month

Method of measurement

Exhale nitric oxide test with Nobreath device

Intervention groups

1

Description

Intervention group: for patients in the intervention group, in addition to routine treatments involving the use of inhaled sprays (airway dilators and corticosteroids) , azithromycin 250 mg capsules twice daily for the first day and then daily for four days. The next is given and from the second week to the twelfth week, three capsules (one day in between) of this capsule are prescribed.

Category

Treatment - Drugs

2

Description

Control group: for patients in the control group, only routine treatments involving the use of inhaled sprays (airway dilators and corticosteroids) will be prescribed for 12 weeks.

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.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hasan Emamian

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

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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

Farnaz Adelnia

Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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)

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