

# 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)

##### Phone

+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

#### Street address

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

#### City

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#### Province

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#### Postal code

3616647555

#### Phone

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#### 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

Farnaz Adelnia

##### Position

General Practitioner

##### Latest degree

Medical doctor

##### Other areas of specialty/work

General Practitioner

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Imam Hossein Hospital, End Imam street, Shahroud, Iran.

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farnazadelnia74@yahoo.com

## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
Dr. Maryam Hajimirghasemi  
**Position**  
Assistant Professor  
**Latest degree**  
Subspecialist  
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Internal Medicine  
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m\_mirghasemi@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**

Dr.Mohammad Bagher Sohrabi

**Position**  
General Practitioner  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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**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