

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The effectiveness of azythromycin in the control of refractory asthma in patients with chronic asthma, a randomized clinical trial

#### Protocol summary

##### Study aim

Determining the effect of azythromycin in the control of refractory asthma patients

##### Design

This is a parallel randomized controlled clinical trial that will be performed on 112 patients with chronic resistant asthma. Randomization in this research is done using quadri blocks using syntax written in SPSS program. The duration of the study will be 2 months.

##### Settings and conduct

This study will conduct as a clinical trial study with 112 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; existence of chronic asthma for at least the last six months; do not take any antibiotics for at least the last one month and conscious consent to participate in research. Exclusion criteria: incidence of any asthma attack during the research period; allergy to azythromycin or intolerance during treatment and existence of infectious and severe respiratory diseases in at least one month.

##### Intervention groups

For patients in the intervention group, in addition to routine treatments involving the use of inhaled sprays (airway dilators and corticosteroids) and oral prednisolone, azythromycin 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) and oral prednisolone will be prescribed for 12 weeks.

##### Main outcome variables

Measuring the severity of chronic asthma and Maximum expiratory volume per second (FEV1)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100102002954N21**

Registration date: **2020-10-03, 1399/07/12**

Registration timing: **prospective**

Last update: **2020-10-03, 1399/07/12**

Update count: **0**

##### Registration date

2020-10-03, 1399/07/12

##### 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

2020-10-21, 1399/07/30

##### Expected recruitment end date

2021-01-18, 1399/10/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

The effectiveness of azythromycin in the control of refractory asthma in patients with chronic asthma, a randomized clinical trial

**Public title**

The effect of azythromycin in the control of refractory asthma patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

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

**Exclusion criteria:**

Incidence of any asthma attack during the research period Allergy to azythromycin or intolerance during treatment Existence of infectious and severe respiratory diseases in at least one month

**Age**

From **15 years** old to **70 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **112**

**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 112 and number of blocks was 28. 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**

3616647555

**Approval date**

2019-12-06, 1398/09/15

**Ethics committee reference number**

IR.SHMU.REC.1398.115

**Health conditions studied****1****Description of health condition studied**

Severe persistent 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 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) and oral prednisolone, azythromycin 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.

### 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) and oral prednisolone 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. Ali Najafi

##### Street address

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

##### City

Shahroud

##### Province

Semnan

##### Postal code

3616611151

##### Phone

+98 23 3234 2000

##### Fax

+98 23 3233 3902

##### Email

anajafi@yahoo.com

## 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

Shahroud

##### Province

Semnan

##### Postal code

3616647555

##### Phone

+98 23 3239 4499

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+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

Afsane Nikravesht

##### Position

General Practitioner

##### Latest degree

Medical doctor

##### Other areas of specialty/work

General Practitioner

##### Street address

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

##### City

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##### Province

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##### Email

a\_nikravesht@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Dr. Ali Najafi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

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**Email**

anajafi@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Dr.Mohammad Bagher Sohrabi

**Position**

General Practitioner

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

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Iran

**City**

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**Province**

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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