Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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 Ssciences 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.
City
Shahroud
Province
Semnan
Postal code
3616611151
Phone
+98 23 3234 2000
Fax
+98 23 3233 3902
Email
m_mirghasemi@gmail.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
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
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
farnazadelnia74@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Dr. Maryam Hajimirghasemi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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
m_mirghasemi@gmail.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
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
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