Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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 Ssciences and Health

Country
Iran (Islamic Republic of)

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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

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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

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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
Afsane Nikravesh

Position
General Practitioner

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Internal Medicine

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Person responsible for updating data

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Latest degree
Medical doctor

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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