Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the effectiveness of Azathioprine and placebo on lung volumes, exacerbations and severity of asthma in severe asthmatic patients

Protocol summary

Study aim

Azathioprine effect on improvement of lung function, asthma severity and exacerbation in severe asthmatic patients, before and after treatment with azathioprine

Design

A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 40 patients. The table of random numbers generated by the calculator is used for randomization.

Settings and conduct

Study population: 40 patients with asthma will be entered based on history and spirometry whose symptoms were uncontrolled despite primary treatments; Location of study: Patients will be selected from among the patients referred to the pulmonary clinic of Imam Khomeini Hospital or those referred to the personal office of university professors in Ahvaz; Blinding type: double blinded - patient and researcher; How to blind: All medicines are placed in similar and dark-colored packages, a numerical label is placed on the medicine box. Only the pharmacist is aware of the number assigned to the relevant group. Then, in order from number 1 to 40, the package of drugs is given to the researcher to prescribe to the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with severe asthma whose symptoms have not improved with usual treatments; Non-inclusion criteria: pregnancy, breastfeeding, advanced liver failure or liver enzymes disorders, advanced renal failure, cytopenia, moderate to severe anemia

Intervention groups

Intervention group: patients receiving azathioprine 2mg/kg daily; Control group: patients receiving placebo.

Main outcome variables

Lung volume (forced expiratory volume in 1 second; Forced vital capacity; Forced expiratory flow at 25–75% of the pulmonary volume); Forced expiratory volume in 1 second to Forced vital capacity ratio; Quality of life in asthmatic patients score; The distance covered in the 6-minute walk test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231219060463N1**
Registration date: **2024-01-16, 1402/10/26**
Registration timing: **prospective**

Last update: **2024-01-16, 1402/10/26**
Update count: **0**

Registration date

2024-01-16, 1402/10/26

Registrant information

Name

Mostafa Ajaman

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-09, 1402/11/20

Expected recruitment end date

2024-08-10, 1403/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Azathioprine and placebo on lung volumes, exacerbations and severity of asthma in severe asthmatic patients

Public title

Azathioprine effect in severe asthmatic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Severe asthmatic patients (FEV1<60) diagnosed by pulmonologist No improvement in symptoms with usual treatments for asthma including Prednisolone 5mg/day, High dose inhaled corticosteroid, Long acting beta agonist and Long acting muscarinic antagonist

Exclusion criteria:

Advanced liver failure Advanced renal failure Pregnancy Breastfeeding Cytopenia Moderate to severe anemia Known allergy to azathioprine Concomitant treatment with: Allopurinol, Febuxostat, Adalimumab, Anakinra Elevated liver enzymes (aminasemia)

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a calculator, random numbers from 1 to 40 are generated, 20 numbers and the first number generated by the calculator are assigned to the intervention group and the next 20 numbers to the control group, then the package of medicines is in the order of number 1 to 40 will be given to the researcher to administer to the patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind, so that both the researcher and the participant do not know about the type of intervention (drug or placebo). All medicines are placed in similar and dark-colored packages, a numerical label is placed on the medicine box. Only the pharmacist is aware of the number assigned to the relevant group. Then, in order from number 1 to 40, the package of drugs is given to the researcher to prescribe to the patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundiahapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd., Golestan Town

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2023-12-18, 1402/09/27

Ethics committee reference number

IR.AJUMS.REC.1402.479

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45.5

ICD-10 code description

Severe persistent asthma

Primary outcomes

1

Description

Mean forced expiratory volume in second 1

Timepoint

Before intervention and three months after intervention

Method of measurement

Spirometry

2

Description

Mean Forced Vital Capacity (FVC)

Timepoint

Before intervention and three months after intervention

Method of measurement

Spirometry

3

Description
Mean forced expiratory flow at 25–75% of forced vital capacity
Timepoint
Before intervention and three months after intervention
Method of measurement
Spirometry

4

Description
Mean asthma related questionnaire score
Timepoint
Before intervention and three months after intervention
Method of measurement
Asthma related questionnaire GSK 2002

5

Description
The number of exacerbations
Timepoint
before intervention and three months after intervention
Method of measurement
History taking

6

Description
Distance traveled in the 6-minute walking test
Timepoint
Before intervention and 3 months after intervention
Method of measurement
6-minute walk test

7

Description
Relative frequency of asthma recovery based on the forced expiratory volume in 1 second
Timepoint
At the end of the study
Method of measurement
Spirometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Azathioprine, 2mg/kg daily tablets for 3 months، made in Ramopharmin pharmaceutical company
Category
Treatment - Drugs

2

Description
Control group: Palcebo, with the same size and shape as azathioprine Produced in the central laboratory of Jundishapur University Faculty of Pharmacy, Ahvaz
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Lung Clinic; Imam Khomeini Hospital
Full name of responsible person
Zahra Mehraban
Street address
Imam Khomeini Hospital, Azadegan Blvd.
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2

Recruitment center
Name of recruitment center
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3

Recruitment center
Name of recruitment center
Private office of Dr. Hamid Borsi
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4

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical 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
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Position
Resident of Internal Medicine
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Demographic information of patients and paraclinical findings of patients in the form of patient code will be provided to other researchers in an unidentifiable manner.

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Other researchers who intend to conduct similar studies with a similar theme and topic

Under which criteria data/document could be used
To conduct studies with a similar theme and topic

From where data/document is obtainable
To get information, they can go to the office of the internal department of Imam Khomeini Hospital in Ahvaz, located on Azadegan Blvd.

What processes are involved for a request to access data/document
After submitting a written request for data request to the internal group office in Imam Khomeini Hospital of Ahvaz and validating the request through the group office, the data will be provided to the researcher after about two weeks.

Comments