

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Azithromycin on airways remodeling in patients with severe refractory asthma

Protocol summary

Study aim

studying the effect of azithromycin on airway remodeling in patients with severe refractory asthma

Design

It is a Randomized, singles center, controlled clinical trial with a parallel group design and double blinded outcomes assessment. Randomization was done by Randomizer website (www.randomizer.org).

Settings and conduct

This study will be done in asthma specialist clinic. After explaining the study for the patients, informed consent will be signed by them if they accept to enter the study. Act Score, severity of dyspnea and coughing, spirometry, FENO (fractional exhaled nitric oxide), lung CT scan and sputum sampling will be done and recorded before and after the treatment. Ct scan measurements will be done by two radiologists who are blinded to the groups and the mean numbers will be used as the final numbers. The sputum will be induced using a jet nebulizer and hyper-tonic saline. It will be kept in -80 degree until use.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients suffering from severe refractory asthma who could not be controlled by high dose corticosteroids and long acting beta2 agonists or by antileukotrienes with or without tiotropium. The FEV1 must be less than 80 percent. Exclusion Criteria: 1- Allergic Bronchopulmonary Aspergillosis 2-Drug allergy 3-Pregnancy or Breast milk feeding 4-Interstitial lung disease such as Vasculitis 5- Recent lung infection 6- Gastroesophageal Reflux

Intervention groups

This study consists of three groups of 25 patients. Patients in the first group takes Azithromycin mg, the next one take Prednisolone 5mg , and last group take Placebo each 12 hours. Patients in each group will take the drugs for 8 months.

Main outcome variables

Need for emergency health services, Act score, FENO, FEV1, outer and outer diameter of bronchuse and

bronchial wall thickness in CT scan, TGF beta gene expression in sputum

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091111002695N8**

Registration date: **2019-05-19, 1398/02/29**

Registration timing: **prospective**

Last update: **2019-05-19, 1398/02/29**

Update count: **0**

Registration date

2019-05-19, 1398/02/29

Registrant information

Name

Majid Mirsadraee

Name of organization / entity

Islamic Azad University- Mashhad branch

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 6694

Email address

majidmirsadraee@mshdiau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-05, 1398/03/15

Expected recruitment end date

2019-09-06, 1398/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of Azithromycin on airways remodeling in patients with severe refractory asthma

Public title
Effect of Azithromycin in refractory asthma

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients suffering from severe refractory asthma who could not be controlled by high dose corticosteroids and long acting beta2 agonists or by antileukotrienes with or without tiotropium. FEV1 must be less than 80 percent.
Exclusion criteria:
Allergic bronchopulmonary aspergillosis Drug allergy
Pregnancy or Breast milk feeding Interstitial lung disease such as Vasculitis Recent lung infection
Gastroesophageal reflux

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
The "Block" randomization method was used to make three treatment groups with block size of 25 for each. Unit of randomization is "individual". Blocks are then randomly chosen to determine the patients' assignment into the groups (Azithromycin, Prednisolone and Placebu). The tool used for randomization was "www.Randomizer.org" website which uses "Math.random" method within the JavaScript programming language to generate its random numbers. Allocation concealment: coded drug containers of identical appearance prepared by an independent group.

Blinding (investigator's opinion)
Double blinded

Blinding description
All the drugs will be prepared with united shape, color and packages. the only difference is the code on the package. The drugs will be given to our colleague who is present in the clinic everyday and is blinded to the types of the drugs and groups of treatment. Each time the patients refer to our clinic they will receive the same drug based on their randomized code.

Placebo

Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Islamic Azad University- Mashhad branch
Street address
Shahin Far Building, sarab alley, Azadi street
City
Mashhad
Province
Razavi Khorasan
Postal code
9178673799

Approval date
2019-05-01, 1398/02/11

Ethics committee reference number
IR.IAU.MSHD.REC.1398.031

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
Bronchial Wall thickness

Timepoint
Before intervention and 8 months after intervention

Method of measurement
Computed tomography (CT) Scan of lung

2

Description
Transforming growth factor beta (TGF-beta) gene expression

Timepoint
Before intervention and 8 months after intervention

Method of measurement
Detecting by Polymerase chain reaction (PCR) of the Sputum

Secondary outcomes

1

Description

Expiratory nitric oxide test with NObreath equipment

Timepoint

Before intervention and 8 months after intervention

Method of measurement

Expiratory nitric oxide test with NObreath equipment

2

Description

Forced expiratory volume in one second (FEV1)

Timepoint

Before intervention and 8 months after intervention

Method of measurement

Micro medical spirometer

3

Description

Asthma control

Timepoint

Before intervention and 8 months after intervention

Method of measurement

Asthma Control Test (ACT) score

4

Description

Number of Need for emergency services because of asthma exacerbation

Timepoint

Before intervention and 8 months after intervention

Method of measurement

Recording the date of asthma exacerbation in the Special Card which will be given to the patients.

Intervention groups

1

Description

Intervention group1: Azithromycin 250mg in form of soft gelatin capsule, one each 12 hours, for 8 months. The Active Pharmaceutical Ingredient is provided by Farabi Pharmaceutical company.

Category

Treatment - Drugs

2

Description

Intervention group2: Prednisolone 5mg in form of soft gelatin capsule, one each 12 hours, for 8 months. The Active Pharmaceutical Ingredient is provided by Alborz Bulk Company.

Category

Treatment - Drugs

3

Description

Control group: Placebo in form of soft gelatin capsule containing Lactose, one each 12 hours, for 8 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Asthma specialist clinic

Full name of responsible person

Majid Mirsadraei

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No 80, 15th Kosar, Kosar Ave., Vakilabad Blv.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Esmaeil Kheirkhah

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Islamic Azad University of Mashhad, Ostad yousefi St., Emamiyeh Blv, Ghasemabad

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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

Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Majid Mirsadraei
Position
Full professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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No 80, 15th Kosar, Kosar Ave., Vakilabad Blv.
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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

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Age Gender Asthma Duration Need for Emergency medical services (before and after treatment) ACT Score (before and after treatment) FEV1 (before and after treatment) FENO(before and after treatment) Bronchial wall thickness in lung CT-scan(before and after treatment) TGF-beta gene expression (before and after treatment)

When the data will become available and for how

long

One Month after publishing the results.

To whom data/document is available

There will be no limitation for accessing the data.

Under which criteria data/document could be used

There will be no limitation for accessing the data. If someone need to use the data, he/she might ask the corresponding author for permission.

From where data/document is obtainable

Contact the corresponding author.

What processes are involved for a request to access data/document

After contacting the corresponding author via phone or Email, the data will be provided.

Comments