

# 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

##### Street address

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

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9187147578

##### Phone

+98 51 3870 4347

##### Email

majidmirsadraee@mshdiau.ac.ir

##### Web page address

<http://drmirsadraee.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Esmaeil Kheirkhah

##### Street address

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

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##### Phone

+98 51 3663 7842

##### Email

research@mshdiau.ac.ir

##### Web page address

<http://vcr.mshdiau.ac.ir/>

#### 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  
**Street address**  
No 80, 15th Kosar, Kosar Ave., Vakilabad Blv.  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University  
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Subspecialist  
**Other areas of specialty/work**  
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<http://drmirsadraee.ir/>

## 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**