Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Oct 2026

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

Protocol summary

Study aim
The effect of Itraconazole on airways 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 nebolizer 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 Itraconazole 100 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 bronchus 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: **IRCT20091111002695N9**
Registration date: **2019-05-25, 1398/03/04**
Registration timing: **prospective**

Last update: **2019-05-25, 1398/03/04**
Update count: **0**

Registration date
2019-05-25, 1398/03/04

Registrant information

Name
Majid Mirsadraee

Name of organization / entity
Islamic Azad University- Mashhad branch

Country
Iran (Islamic Republic of)

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+98 51 3841 6694

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-10, 1398/03/20

Expected recruitment end date
2019-09-11, 1398/06/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

effect of Itraconazole in severe 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 should 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

By using the Randomizer website (https://www.randomizer.org/) 75 codes will be divided into 75 groups of Itraconazole, Prednisolone and Placebu.

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

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.1398.030

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 in the sputum

Timepoint

Before intervention and 8 months after intervention

Method of measurement

Detecting by Polymerase chain reaction (PCR) of the Sputum

Secondary outcomes

1

Description

Fraction of expiratory Nitric Oxide (FENO)

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 group 1: Itraconazole 100 mg in form of soft gelatin capsule, one each 12 hours, for 8 months. This drug is provided by Alborz Darou Company.

Category

Treatment - Drugs

2

Description

Intervention group2: Prednisoline 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

Placebo

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

Street address

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

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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

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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. If someone need to use the data, he/she might ask the corresponding author for permission.

Under which criteria data/document could be used
there is no limitation.

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