

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison effects of Itraconazole and Prednisone on Fibroblast Growth Factor 2 gene expression, clinical manifestation and other tests in patients with persistent severe asthma

Protocol summary

Study aim

Comparison effects of Itraconazole and Prednisone on Fibroblast Growth Factor 2 gene expression, clinical manifestation and other tests in patients with persistent severe asthma

Design

Interventional clinical trial in 2 - 3 phase with control group, design of 70 patients as a sample group, parallel groups, double blind, using permuted block randomization by STATA software and concealed in numbered drug containers.

Settings and conduct

In pulmonary private office after filling questionnaire including asking about clinical manifestation and asthma control test, spirometry respiratory test, analyzing lung ct scan and rule out of other diseases, counting blood cells and being in definition of severe asthma as well, 70 randomized patients will participate in study after taking phlegm smear in two itraconazole and prednisone groups then after 32 weeks all tests will take again, blinding by numbered uniform drug containers that is not assignable for patients and office staff.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age older than 18 years old; no response to high dose inhaled corticosteroids and long acting beta agonist with antileukotriene; forced expiratory volume in one second less than 80 percent with fungal sensitization. Exclusion criteria: drug interaction or sensitivity to Itraconazole; pregnancy or breastfeeding periods; interstitial disease like vasculitis or churg strauss; severe heart disease; being smoker.

Intervention groups

In experimental group Itraconazole capsule 100 mg twice a day and in control group prednisone capsule 5mg twice a day with uniform containers and lable

Main outcome variables

Wheezing; decreasing Fgf2 expression; reducing the

number of eosinophils and neutrophils in sputum; increasing spirometric parameters; decreased expiratory nitric oxide; increased bronchial diameter on CT scan

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181225042116N1**

Registration date: **2020-12-18, 1399/09/28**

Registration timing: **prospective**

Last update: **2020-12-18, 1399/09/28**

Update count: **0**

Registration date

2020-12-18, 1399/09/28

Registrant information

Name

Mahsa Manafi Varkiani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3605 5216

Email address

mahsafall_2005@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effects of Itraconazole and Prednisone on Fibroblast Growth Factor 2 gene expression, clinical manifestation and other tests in patients with persistent severe asthma

Public title

Comparison effects of Itraconazole and Prednisone in patients with persistent severe asthma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age older than 18 years old No response to high dose inhaled corticosteroids and long acting beta agonist with antileukotriene Forced expiratory volume in one second less than 80 percent Fungal sensitization

Exclusion criteria:

Sensitivity and drug interaction with Itraconazole History of taking Itraconazole Gastroesophageal reflux disease Known and untreated Severe heart disease Known liver and kidney disease Chronic eosinophilic pneumonia Charge Strauss syndrome Chronic Obstructive Pulmonary Disease Total IgE more than 1000IU/ml Pregnancy or breastfeeding Lack of access to Appropriate RNA in patient sputum sample Sarcoidosis Hypersensitivity pneumonitis Impaired vocal cords Filarisis Central airway obstruction Sleep apnea

Age

From 18 years old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of individuals to study groups is a block randomization method using 7 blocks of 10; This is done with stata software version 16, this software generates random groups, each block has 5 people in the intervention group and 5 people in the control group, whose order is also random and the numbers assigned to each person are different then labeled onto medicine boxes that have the same shape , and all ten drugs that belong to a block are placed in a separate package, and one is randomly picked and given to the patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

All drugs, both prednisone and itraconazole, have been purchased from the pharmaceutical company in the form of a pure white substance. Then, the drugs are filled in capsules of the same size and color with the cooperation of Mashhad School of Pharmacy; medicine cans are packed in the same shape with the same drug label, random numbers are pasted on them and placed in packs of 10 that are already divided into blocks, then these packages are transferred to a specialized asthma clinic. then nurse is given a can of medicine to the patient after the doctor's examination and being included in the criteria for studying. At the end of each course of the drug, the same can of medicine with the previous code is given again until the end of the study. Also, the person entering the information in Excel enters all the patient information only according to the code on the medicine. During the study, none of the people are aware of the type of medicine used. At the end of the study, the person who had no role in the study is asked to Assign 1 and 2 to the table of random numbers for each drug that can be analyzed for statistics without knowing the drug.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Central Organization of Islamic Azad University

Street address

Bazarche Sarab Ave., Imam Khomeini Blvd,

City

Mashhad

Province

Razavi Khorasan

Postal code

9133745938

Approval date

2020-08-05, 1399/05/15

Ethics committee reference number

IR.IAU.MSHD.REC.1399.088

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

Fibroblast growth factor2 gene expression measurement

Timepoint

Measuring fibroblast growth factor 2 gene expression before intervention and 8 months after taking Itraconazole drug or prednisone

Method of measurement

Real time Polymerase Chain Reaction

2

Description

Number of sputum eosinophils and neutrophils

Timepoint

Before intervention and 8 months after treatment

Method of measurement

Preparation of thin smear after sputum centrifugation with DDT 0.01%, and staining with hematoxin and eosin and counting with light microscope

3

Description

Bronchial size changes include bronchial thickness, internal lumen, external lumen, wall area percentage

Timepoint

Before intervention and 8 months after treatment

Method of measurement

Chest High-resolution computed tomography

4

Description

Spirometric parameters include FEV1, FVC, Fef25-75

Timepoint

Before intervention and 8 months after treatment

Method of measurement

Spirometer device

Secondary outcomes

1

Description

Measurement of fractional nitric oxide concentration in exhaled breath

Timepoint

Before the intervention and after 8 months of treatment

Method of measurement

Bedfont NO breath device for Measuring nitric oxide

2

Description

Asthma Symptom Questionnaire

Timepoint

Before the intervention and after 8 months of treatment

Method of measurement

Asthma control questionnaire (ACQ)

3

Description

Clinical symptoms of patients include wheezing

Timepoint

Before the intervention and after 2 weeks, then every month until the end of the treatment period

Method of measurement

According to the examination by stethoscope

Intervention groups

1

Description

The first intervention group: Itraconazole capsules 100 mg twice a day for 8 months Tehran Daru company

Category

Treatment - Drugs

2

Description

Control group: prednisone tablets 5 mg twice a day for 8 months Iran Hormone company

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Private lung office

Full name of responsible person

Mahsa Manafi Varkiani

Street address

No50.,Faramarz Abbasi38.,Ferdowsi Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9197948937

Phone

+98 51 3605 5216

Email

mahsafall_2005@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Saeed Abtahi

Street address

Bazarche Sarab Ave., Imam Khomeini Blvd,

City

Mashhad

Province

Razavi Khorasan

Postal code

9133745938

Phone

+98 51 3225 0041

Email

ethics.mshdiau@gmail.com

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

Mahsa Manafi Varkiani

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

No.50, Faramarz Abbasi 38, Ferdowsi Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9197948937

Phone

+98 51 3605 5216

Fax**Email**

mahsafall_2005@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Majid Mirsadraee

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

pulmonary, allergy

Street address

Iman Building., Between 4th and 6th Noth Kosar., Vakilabad Blvd,

City

mashhad

Province

Razavi Khorasan

Postal code

91977958963

Phone

+98 51 3605 5216

Email

mahsafall_2005@yahoo.com

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

Islamic Azad University

Full name of responsible person

Mahsa Manafi Varkiani

Position

student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

NO.50, Faramarz Abbasi 38 Ave., Ferdowsi Blvd.,

City

mashhad

Province

Razavi Khorasan

Postal code

9197948937

Phone

+98 51 3605 5216

Fax**Email**

mahsafall_2005@yahoo.com

Web page address**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

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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