

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the efficacy and side effects of desloratadine with fexofenadine on allergic rhinitis in patients referred to Masih Daneshvari Hospital

Protocol summary

Study aim

Evaluation of the effect and side effects of desloratadine in comparison with fexofenadine on allergic rhinitis in patients referred to Masih Daneshvari Hospital

Design

This study is a double-blind clinical trial and randomized groups with simple randomization and phase 2 method on 65 patients with allergic rhinitis. In the first group, patients are treated with desloratadine, and in the second group, they are treated with fexofenadine.

Settings and conduct

Patients with allergic rhinitis referred to Masih Daneshvari Hospital in Tehran are randomly divided into two groups. In group A, patients will receive desloratadine at a dose of 5 mg daily for 4 weeks, and in group B, they will receive 120 mg daily fexofenadine for 4 weeks. Both groups will not receive medication for two weeks. Group A is then given fexofenadine and group B is given desloratadine for four weeks. The study is two-blind, and medications are given to the patient in labeled packages, and patients are kept blind to group assignments. Also, the drug distributor colleague is not aware of this labeling.

Participants/Inclusion and exclusion criteria

Age over 12 years, history of allergic rhinitis or diagnosis at the first visit, written consent

Intervention groups

The first group was treated with 5 mg of desloratadine daily for 4 weeks and the second group was treated with 120 mg of fexofenadine daily for 4 weeks. After stopping the drug for two weeks, the first group received fexofenadine for 4 weeks and the second group received desloratadine for 4 weeks.

Main outcome variables

Clinical symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160516027929N11**

Registration date: **2021-09-25, 1400/07/03**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-25, 1400/07/03**

Update count: **0**

Registration date

2021-09-25, 1400/07/03

Registrant information

Name

Atefeh Fakharian

Name of organization / entity

National research institute of tuberculosis and lung diseases

Country

Iran (Islamic Republic of)

Phone

+98 21 2712 2541

Email address

afakharian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-12-06, 1400/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy and side effects of desloratadine with fexofenadine on allergic rhinitis in patients referred to Masih Daneshvari Hospital

Public title

Comparison of the efficacy and side effects of desloratadine with fexofenadine on allergic rhinitis in patients referred to Masih Daneshvari Hospital

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 12 years History of allergic rhinitis or diagnosis at first visit Written consent to participate in the study

Exclusion criteria:

Sensitivity, allergy or adverse reaction to desloratadine and fexofenadine Patients who have previously been treated with two or more drugs pregnancy and breastfeeding

Age

From **12 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **65**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: simple randomization, randomization unit: individual, randomization tool: table of random numbers, To construct a random sequence with the help of a random number table and by the statistical consultant, patients accidentally had one of the even and odd codes. Patients who were assigned even numbers were in the first group and patients with odd codes were in the second group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drugs are placed in bags that are similar in appearance and are labeled as groups A and B. The patient is unaware of this labeling (aware of receiving medication but kept blind to group assignments). Also, the project partner who distributes the medicine is not aware of this labeling. To avoid any possible complications, the lead researcher is aware of the assignment of groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Arabi St., Yemen St., Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717434

Approval date

2020-09-22, 1399/07/01

Ethics committee reference number

IR.SBMU.NRITLD.REC.1400.024

Health conditions studied**1****Description of health condition studied**

Allergic rhinitis

ICD-10 code

J30.1

ICD-10 code description

Allergic rhinitis due to pollen

Primary outcomes**1****Description**

General clinical symptoms

Timepoint

Before starting treatment and 10 weeks after starting treatment

Method of measurement

Rhinitis Quality of Life Questionnaire

2**Description**

The severity of eye symptoms

Timepoint

Rhinitis Quality of Life Questionnaire

Method of measurement

Rhinitis Quality of Life Questionnaire

3**Description**

Severe itching in the nose

Timepoint

Rhinitis Quality of Life Questionnaire

Method of measurement

Rhinitis Quality of Life Questionnaire

4**Description**

sleep disorders

Timepoint

Rhinitis Quality of Life Questionnaire

Method of measurement

Rhinitis Quality of Life Questionnaire

Secondary outcomes**1****Description**

Evaluation of the clinical symptoms of allergic rhinitis

Timepoint

Before starting treatment and 10 weeks after starting treatment

Method of measurement

Physical examination

Intervention groups**1****Description**

Intervention group: In the first group, patients receive 5 mg of desloratadine daily for 4 weeks. After 2 weeks of no drug treatment, they are treated with fexofenadine 120 mg daily for 4 weeks.

Category

Treatment - Drugs

2**Description**

Intervention group: In the second group, patients received 120 mg of fexofenadine daily for 4 weeks. After two weeks of no drug treatment, they are treated with desloratadine.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Masih Daneshvari Hospital

Full name of responsible person

Atefeh Fakharian

Street address

Darabad, Shahid Bahonar St. (Niavaran)

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1956944413

Phone

+98 21 2610 5050

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fakharian_2005@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Shahid Abbas Arabi St., Shahid Chamran Highway

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198396411

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Email

Mpajouhesh@sbmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Atefeh Fakharian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is currently no program

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