Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
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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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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 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