Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effectiveness of desloratadine plus montelukast combination therapy and desloratadine monotherapy on quality of life in patients with persistent allergic rhinitis

Protocol summary

Study aim

Determining and comparing the effect of combination therapy of des loratadine and montelukast with single drug treatment of des loratadine on the quality of life of patients with stable allergic rhinitis in the Kashan in 2020.

Design

Clinical trial with control group, with parallel group design, double-blind, randomized, phase 2 on 56 patients. For randomization from www.sealedenvelope.com/simple-randomiser/v1/lists and Balanced (permuted) block randomization method was used

Settings and conduct

Preliminary sampling is performed from the ENT clinic of Matini Hospital in Kashan. This study was prepared as double-blind by an expert who did not participate in the study. In such a way that two types of drug packages named A and B were prepared and delivered for using in the control and intervention groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with allergic rhinitis who are symptomatic for more than 4 weeks and also more than 4 days a week; Existence of persistent allergic rhinitis during the last 2 years; Age of 65-18 years old. Non inclusion criteria: Reluctance to cooperate; Severe upper respiratory tract disease during the 6 weeks prior to study; Nasal polyp or nasal septum aberration; Acute or chronic rhinosinusitis; Smoking; Bronchial asthma; Antihistamine use in the last 1 month

Intervention groups

Control group: single drug treatment with des loratadine and placebo. In this group, 5 mg des loratadine tablets are used every night for 6 weeks. The placebo is also used similar to the Montelukast protocol. Intervention group: Treatment with two drugs, des loratadine and montelukast. In this group, 5 mg tablets of des loratadine are used every night for 6 weeks. In this study, Montelukast is used one 10-mg tablet per night for 6 weeks.

Main outcome variables

Quality of life; Runny nose; stuffy nose; sneezing; itching

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200909048677N1**
Registration date: **2020-10-05, 1399/07/14**
Registration timing: **retrospective**

Last update: **2020-10-05, 1399/07/14**
Update count: **0**

Registration date

2020-10-05, 1399/07/14

Registrant information

Name

Shayan Ramezanpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0026

Email address

ramezanpour-sh@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of desloratadine plus montelukast combination therapy and desloratadine monotherapy on quality of life in patients with persistent allergic rhinitis

Public title
Comparing the effectiveness of combination therapy and monotherapy on quality of life in patients with persistent allergic rhinitis
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with allergic rhinitis who are symptomatic for more than 4 weeks and also more than 4 days a week Existence of persistent allergic rhinitis during the last 2 years Age 18-65 years
Exclusion criteria:
unwillingness to cooperate Severe upper respiratory tract disease during the 6 weeks prior to the study Nasal polyps or deviation of the nasal septum Acute or chronic rhinosinusitis smoking Bronchial asthma Pregnancy or breastfeeding Taking antihistamines during the last 1 month Use of systemic or topical corticosteroids History of allergies to Montelukast or Des Loratadine
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
To randomly assign each sample to intervention and control groups, first create a randomization list using the website www. sealedenvelope.com/simple-randomiser/v1/lists and was prepared by Balanced (permuted) block randomization method. According to the entry turn of each sample to the study and random sequence, the individuals are assigned to one of the two groups A (control group) and B (intervention group).
Blinding (investigator's opinion)
Double blinded
Blinding description
Two types of medication packages, called A and B, were designed by an expert who did not participate in the study. One package contained des loratadine tablets and Montelukast tablets. And the other package included des lortadine tablets and placebo.It should be noted that the placebo was quite similar to Montelukast in shape, color and size.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kashan University of Medical Sciences
Street address
Kashan University of Medical Sciences, Ghotb-e-Ravandi boulevard
City
kashan
Province
Isfehan
Postal code
8715973474
Approval date
2020-09-01, 1399/06/11
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1399.083

Health conditions studied

1

Description of health condition studied
allergic rhinitis
ICD-10 code
J30
ICD-10 code description
Vasomotor and allergic rhinitis

Primary outcomes

1

Description
Quality of life score
Timepoint
Once before starting treatment and once 6 weeks after starting treatment.
Method of measurement
mini-RQLQ checklist

Secondary outcomes

1

Description
Runny nose
Timepoint
Once before treatment and once 6 weeks after
Method of measurement
Nasal symptom score checklist. The severity of these symptoms is assessed based on the nasal symptom score. In this questionnaire, the patient scores the 4 main symptoms of allergic rhinitis from 0 (absence of the desired symptom) to 3 (severe).

2

Description
Sneezing
Timepoint
Once before treatment and once 6 weeks after.
Method of measurement
Nasal symptom score checklist. The severity of these symptoms is assessed based on the nasal symptom score. In this questionnaire, the patient scores the 4 main symptoms of allergic rhinitis from 0 (absence of the desired symptom) to 3 (severe).

3

Description
Nasal congestion
Timepoint
Once before treatment and once 6 weeks after.
Method of measurement
Nasal symptom score checklist. The severity of these symptoms is assessed based on the nasal symptom score. In this questionnaire, the patient scores the 4 main symptoms of allergic rhinitis from 0 (absence of the desired symptom) to 3 (severe).

4

Description
Itching
Timepoint
Once before treatment and once 6 weeks after.
Method of measurement
Nasal symptom score checklist. The severity of these symptoms is assessed based on the nasal symptom score. In this questionnaire, the patient scores the 4 main symptoms of allergic rhinitis from 0 (absence of the desired symptom) to 3 (severe)

Intervention groups

1

Description
Intervention group: The recipient group is a combination of desloratadine and Montelukast. In this study, 5 mg des loratadine tablets made by Abidi Pharmaceutical Company, 1 tablet every night for 6 weeks of intervention are used. In addition, 10 mg Montelukast tablets made by Abidi Pharmaceutical Company are used, 1 tablet every night for 6 weeks of intervention. During this period, the use of drugs is controlled by telephone.
Category
Treatment - Drugs

2

Description
Control group: group of des loratadine and placebo. In this study, 5 mg des loratadine tablets made by Abidi Pharmaceutical Company, 1 tablet every night for 6 weeks of intervention are used. In addition placebo which is quite similar to Abidi's Montelukast tablet and is made from the same company is used.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashan Matini Hospital Clinic
Full name of responsible person
Shayan Ramezanpour
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Amirkabir street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

personal

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Shayan Ramezanpour

Position

intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Assistant Professor

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Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Latest degree

A Level or less

Other areas of specialty/work

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dr.sh.ramezanpour@gmail.com

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