Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of montelukast and intranasal antihistamine in treatment of moderate to severe allergic rhinitis in Shiraz Emam Reza Clinic in 2020

Protocol summary

Study aim

1)Evaluation the quality of life in moderate to severe allergic rhinitis via SNOT22 questionnaire; 2) Evaluation the quality of life in patients with moderate to severe allergic rhinitis in three groups after treatment with Montelukast and nasal corticosteroids and after treatment with azalastine and nasal corticosteroids and nasal corticosteroids alone with SNOT22; 3)Evaluation the effect of each treatment on the control of underlying asthma, if exists

Design

Three groups of 22 patients with moderate to severe allergic rhinitis were divided into three groups based on the clinic file number. Phase 3 clinical trial was performed to evaluate the effectiveness of each treatment.

Settings and conduct

This study is performed on patients referred to the Allergy Clinic of Imam Reza Clinic in Shiraz. First, patients' information is recorded and then the SNOT22 questionnaire is filled in by them. Depending on the intervention group, treatment is started and the forms are filled out again within three months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) age of patients under 6 years and over 50 years old; 2) moderate to severe allergic rhinitis. Exclusion criteria: 1) drug allergy; 2) infectious rhinitis; 3) patients with chronic diseases; 4) taking other drugs and immunotherapy

Intervention groups

The first group consisted of 22 patients will receive montelukast and budesonide nasal spray .The second group with 22 patients will receive intranasal antihistamines (Azelastine) with a dose of one puff twice a day for patients between 6 and 12 years and two puffs twice a day for patients older than 12 years and a nasal spray and budsonide. The third group consisted of 22 patients will use only the intranasal corticosteroid budesonide.

Main outcome variables

Patients' quality of life (SNOT22 questionnaire score), spirometry variables in case of asthma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200906048642N1**
Registration date: **2020-09-16, 1399/06/26**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-16, 1399/06/26**
Update count: **0**

Registration date

2020-09-16, 1399/06/26

Registrant information

Name

Nasrin Mortazavi Far

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4334

Email address

nasrinmortazavi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-02-19, 1399/12/01

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

Scientific title
Comparative study of montelukast and intranasal antihistamine in treatment of moderate to severe allergic rhinitis in Shiraz Emam Reza Clinic in 2020

Public title
Comparison of montelukast and intranasal antihistamine in allergic rhinitis treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Moderate to severe allergic rhinitis Seasonal and perennial allergic rhinitis
Exclusion criteria:
Mild or intermittent allergic rhinitis Chronic diseases under treatment(chronic kidney disease,hypertension,diabetes mellitus) History of drug reaction Immunotherapy Infectious rhinosinusitis
Age
From **6 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
According to clinic reception number, the patients divided respectively to two intervention and one control group
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Shiraz university of Medical Science, Zand street, Shiraz
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2020-07-20, 1399/04/30
Ethics committee reference number
IR.SUMS.MED.REC.1399.242

Health conditions studied

1

Description of health condition studied
Allergic rhinitis
ICD-10 code
J30.9
ICD-10 code description
Allergic rhinitis, unspecified

Primary outcomes

1

Description
Quality of life via SNOT22
Timepoint
Monthly up to 3 months
Method of measurement
SNOT22 questionnaire

Secondary outcomes

1

Description
Patient symptoms
Timepoint
Monthly to 3 months
Method of measurement
SNOT22 questionnaire

Intervention groups

1

Description
Intervention group: Treatment group with Montelukast and Budesonide nasal spray in this group consisting of 22 patients.Montelukast Dr.Abidi factory with a dose of 5 mg per day to patients aged 6 to 14 years and 10 mg per day to patients older than 14 years and budesonide nasal spray twice a day, one puff is prescribed for patients over 6years and once a day, one intranasal puff to patients aged6-14 years. Treatment lasts for three

months. The patient's symptoms are checked monthly.

Category

Treatment - Drugs

2

Description

Intervention group: Azelastine nasal spray and budesonide nasal spray. Treatment group with azalastine nasal spray and budesonide nasal spray with 22patients receiving intranasal antihistamine (Azelastine) with a dose of one puff twice a day for patients between 6 to 12 years and two puffs twice a day for patients older than 12 years and budsonide nasal spray is prescribed. Azalastine (Zelex) spray produced by World Health Pharmaceutical Company, which was prescribed for three months of treatment.

Category

Treatment - Drugs

3

Description

Control group: nasal spray budesonide (Naxonella spray 64 micrograms / dose 120 puffs) which is administered two puff intranasal twice daily for older than 12years and for6-12 years twice daily one puff intranasally. Standard treatment for moderate to severe allergic rhinitis is nasal corticosteroid spray which in this study is budesonide and the same dose is used in all groups.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza clinic of Shiraz University of Medical Sciences

Full name of responsible person

Nasrin Mortazavi Far

Street address

Imam Reza Clinic, Namazi Square, Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezayian Zade

Street address

Shiraz University of Medical Science ,Zand street,Shiraz

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Nasrin Mortazavi Far

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Immunology

Street address

Pediatric department-Namazi Hospital _Namazi Square-Shiraz

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Person responsible for scientific inquiries

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Person responsible for updating data

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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