Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the Effectiveness of Cromolyn Sodium Mometasone and Azelastine Nasal Sprays' in Improving Nasal Symptoms in Patients with Moderate to Severe Persistent Allergic Rhinitis.

Protocol summary

Study aim

Evaluation and comparison of the efficacy of Cromolyn sodium , Mometazone, and Azelastin in improving nasal symptoms in patients with moderate to severe persistent Allergic Rhinitis.

Design

A Phase 2, randomized, double blind, parallel-group, controlled clinical trial involving 108 patients; Random Allocation software was used for randomization.

Settings and conduct

Patient symptoms are assessed and scored using the Total Nasal Symptom Score (TNSS). This questionnaire comprises four components nasal congestion, rhinorrhea, sneezing, and nasal itching each scored from 0 to 3 based on symptom severity, resulting in a total score ranging from 0 to 12. Patients will be evaluated on two occasions: day one (prior to initiating medication) and day twenty-eight (after starting medication); necessary information will be collected from the patients and recorded on data forms. Matching for age and sex will be performed, and the study will be conducted in a double-blind manner using identical spray containers prepared by a pharmacist and assigned to three groups ;ensuring that neither the administrator nor the patient is aware of the specific spray type. The study will be conducted at the Al-Zahra ENThospital in Zahedan.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with a confirmed diagnosis of Allergic Rhinitis; age 18–50 years; moderate-to-severe Allergic Rhinitis based on symptom severity; and provision of written informed consent to participate in the study.

Intervention groups

For Sodium Cromoglicate, the dosage is one spray in each nostril, four times daily; For Azelastin, is one spray in each nostril, twice daily; For Mometazone is one spray in each nostril, twice daily.

Main outcome variables

Recipients of mometasone spray in the control group are compared with recipients of azelastine and cromolyn sodium sprays regarding their response to treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260919071117N1**
Registration date: **2026-10-02, 1405/07/10**
Registration timing: **prospective**

Last update: **2026-10-02, 1405/07/10**
Update count: **0**

Registration date

2026-10-02, 1405/07/10

Registrant information

Name

Elham Jannesari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-23, 1405/08/01

Expected recruitment end date

2027-05-20, 1406/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Cromolyn Sodium Mometasone and Azelastine Nasal Sprays' in Improving Nasal Symptoms in Patients with Moderate to Severe Persistent Allergic Rhinitis.

Public title

Effectiveness of Cromolyn Sodium Mometasone and Azelastine Nasal Sprays' in Allergic Rhinitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with definite diagnosis of Persistent Allergic Rhinitis based on ARIA criteria, whose symptoms are present more than 3 days a week and for more than 3 consecutive weeks. Age between 18 and 50 years Suffering from moderate to severe allergic rhinitis based on the severity of symptoms which include:Sleep disorder caused by symptoms.Disruption in daily activities including work, education, sports and leisure time. Existence of annoying and chronic symptoms including rhinorrhea (runny nose), congestion, sneezing and itchy nose. Informed written consent to participate in the research.

Exclusion criteria:

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

They are placed randomly in a block way (using Random Allocation software) in three equal spheres. With box unit.

Blinding (investigator's opinion)

Double blinded

Blinding description

A pharmacist has coded three spray medications—packaged in containers identical in color, shape, and volume as Code 1, Code 2, and Code 3, with each code corresponding to a specific drug. A clinical caregiver hands one of the coded sprays to each patient for use, while neither the patient nor the caregiver knows which drug corresponds to which code. Ultimately, following an analysis by the researchers, the specific drug associated with each code is revealed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences.

Street address

Zahedan university of medical science, Daneshgah street.

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Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2026-08-24, 1405/06/02

Ethics committee reference number

IR.ZAUMS.REC.1405.171

Health conditions studied

1

Description of health condition studied

Allergic Rhinitis.

ICD-10 code

J30.8

ICD-10 code description

Other allergic rhinitis

Primary outcomes

1

Description

Nasal symptoms.

Timepoint

Day 1 before starting the medication and Day 28 after administration.

Method of measurement

Total nasal symptom score Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Cromolyn spray
Category
Treatment - Drugs

2

Description
Intervention group: Azelastin Spray
Category
Treatment - Drugs

3

Description
Intervention group: Mometasone spray group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al Zahra hospital
Full name of responsible person
Elham Jannesari
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Motahari hospital
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Sponsors / Funding sources

1

Sponsor
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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
Zahedan medical center
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
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Position
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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
No information exist.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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