Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Adding Azelastine Hydrochloride to Fluticasone Propionate Nasal Spray in the Treatment of Allergic Rhinitis

Protocol summary

Study aim

To evaluate and compare the effectiveness of combination therapy with fluticasone propionate and azelastine hydrochloride nasal spray versus fluticasone propionate monotherapy in improving the symptoms of patients with allergic rhinitis.

Design

Randomized, single-blind, two-arm parallel group clinical trial with concealed block randomization. A total of 80 patients will be enrolled and randomly allocated in a 1:1 ratio to treatment groups.

Settings and conduct

This study is conducted at the outpatient otolaryngology and head & neck surgery clinic of Imam Reza Hospital, affiliated with Tabriz University of Medical Sciences, Iran.

Participants/Inclusion and exclusion criteria

Participants must meet the following conditions: age above 12 years, SFAR score ≥ 7 as a diagnostic indicator of allergic rhinitis, residency in East Azerbaijan province, presence of persistent allergic rhinitis symptoms based on clinical history, willingness to attend all study visits and follow-ups, and provision of a signed informed consent form to participate in the research. Patients will be excluded if they have had an upper or lower respiratory tract infection in the past two weeks, structural nasal abnormalities such as severe septal deviation, polyps, or tumors, or a history of previous nasal or paranasal sinus surgery.

Intervention groups

Intervention Group: Forty patients in this group will receive a combination nasal spray consisting of fluticasone propionate (50 mcg) and azelastine hydrochloride (140 mcg) daily. The medication will be administered in a standard dose as prescribed by the physician. Control Group: Forty patients in this group will receive a nasal spray containing fluticasone propionate (50 mcg) alone, which represents the current standard therapy.

Main outcome variables

Change in allergic rhinitis symptom severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250927067374N1**
Registration date: **2025-09-29, 1404/07/07**
Registration timing: **prospective**

Last update: **2025-09-29, 1404/07/07**
Update count: **0**

Registration date

2025-09-29, 1404/07/07

Registrant information

Name

Mahdi Zohouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 930 226 1479

Email address

zohouri.mahdi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2026-03-19, 1404/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of Adding Azelastine Hydrochloride to Fluticasone Propionate Nasal Spray in the Treatment of Allergic Rhinitis

Public title
Effect of Combination Nasal Spray of Fluticasone and Azelastine in Improving Symptoms of Allergic Rhinitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
SFAR score ≥ 7 indicating allergic rhinitis Residency in East Azerbaijan province Presence of persistent symptoms of allergic rhinitis based on medical history Signed informed consent to participate in the study Willingness to adhere to follow-up visits throughout the study period

Exclusion criteria:
Upper or lower respiratory tract infection within two weeks prior to the first visit Structural nasal abnormalities such as severe septal deviation, nasal polyps, or tumors History of previous nasal or paranasal sinus surgery Need for surgical treatment during the study period Use of systemic or oral corticosteroids within 30 days prior to the first visit Pregnant or breastfeeding women Presence of serious underlying diseases such as asthma, diabetes, cancer, or rheumatic diseases Unreliable or uncooperative patients, such as those with severe depression or intellectual disability Known allergy to antihistamines or corticosteroids

Age
From **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomization will be performed using a block randomization method with variable block sizes (4 and 6) and an allocation ratio of 1:1. The random sequence will be generated by an independent statistician using computer software and kept secure in sequentially numbered, opaque, sealed envelopes (SNOSE) to ensure allocation concealment. After confirming eligibility, the next envelope in sequence will be opened, and the patient's group assignment will be determined.

Blinding (investigator's opinion)
Single blinded

Blinding description
Since the principal investigator is also the treating physician, blinding is not feasible for them; however, data collection and statistical analysis will be performed by an independent blinded assessor, making this a single-blind clinical trial.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Vice chancellor for research, Tabriz University of Medical Sciences

Street address
Vice chancellor for research, Tabriz University of Medical Sceinces, Daneshgah Square

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2025-09-14, 1404/06/23

Ethics committee reference number
IR.TBMZED.REC.1404.406

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
Change in Total Symptom Score

Timepoint
Baseline and week 4 after treatment

Method of measurement
Four-point symptom scale (FDA criteria for allergic rhinitis)

Secondary outcomes

1

Description
Change in ocular symptoms
Timepoint
Baseline and week 4 after treatment
Method of measurement
Four-point symptom scale (FDA criteria for allergic rhinitis)

2

Description
Patient satisfaction with treatment
Timepoint
4 week after treatment
Method of measurement
Visual Analog Scale

Intervention groups

1

Description
Intervention group: Patients in this group will receive a combination nasal spray containing fluticasone propionate (50 mcg) and azelastine hydrochloride (140 mcg), administered daily in a standard dosage as prescribed by the physician.
Category
Treatment - Drugs

2

Description
Control group: Patients in this group will receive a nasal spray containing fluticasone propionate (50 mcg) alone, representing the current standard of care.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Dr. Shahin Abdollahi Fakhim
Street address
ENT ward, floor 2, Imam-Reza hospital, In front of the university's main building, Golgasht street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 914 372 1343
Fax
+98 41 3335 2073
Email
imamreza@tbzmed.ac.ir
Web page address
https://imamreza.tbzmed.ac.ir/?PageID=734

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Khosrow Adibkia
Street address
Vice chancellor for research, Tabriz University of medical sceinces, Daneshgah square
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Phone
+98 41 3335 7310
Fax
+98 41 3334 4280
Email
adibkia@tbzmed.ac.ir
Web page address
https://researchvice.tbzmed.ac.ir/Page-497
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Mahdi Zohouri
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work

Ear, Nose, and Throat

Street address
Department of ENT, floor 2, Emam-Reza hospital, Daneshgah street

City
Tabriz

Province
East Azarbaijan

Postal code
5166614756

Phone
+98 930 226 1479

Fax

Email
zohouri.mahdi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mahdi Zohouri

Position
Resident

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Email
zohouri.mahdi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

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Mahdi Zohouri

Position
Resident

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Study data is categorized and coded with no identifiable individuals.

When the data will become available and for how long
Access to study data after publication of the result is available in the journal.

To whom data/document is available
Anyone interested in using the data can access the study data.

Under which criteria data/document could be used
Study data can be used for comparison with other results.

From where data/document is obtainable
Refer to the study's scientific or public accountability person for data.

What processes are involved for a request to access data/document
The request will be sent by email to person responsible for scientific or public inquiries.

Comments