Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Efficacy of Combined Spray (Fluticasone + Azelastine) Spray versus Single-Agent Use of Fluticasone Spray and Azelastine Spray in Improving Clinical Symptoms and Adenoid Size in Children with Adenoid Hypertrophy - Clinical Trial

Protocol summary

Study aim

To compare clinical symptom severity based on the Berlucchi criteria, adenoid size by endoscopy and radiography, and the efficacy of three treatments in improving symptoms and quality of life, reducing adenoid size, and preventing adverse drug effects in children with adenoid hypertroph

Design

This is a Phase III, randomized, single-blind, parallel-group, three-arm clinical trial involving 90 children aged 6–12 years with adenoid hypertrophy. Participants will be randomly allocated to three groups of 30.

Settings and conduct

The study will be conducted at Amir Al-Momenin Educational and Medical Center/Hospital in Rasht. Ninety eligible children will be randomly allocated into three groups of 30 participants receiving combination azelastine/fluticasone, fluticasone, or azelastine nasal spray and followed for 12 weeks. Outcome assessors and data analyzer will be blinded to group allocation, and clinical symptoms, adenoid size, quality of life, and adverse drug effects will be assessed and compared among the groups.

Participants/Inclusion and exclusion criteria

Inclusion: Children aged 6–12 years with confirmed adenoid hypertrophy, symptoms for ≥3 months, normal or Grade 1–2 tonsils, and parental consent. Exclusion: Recent corticosteroid, antihistamine or decongestant use; drug hypersensitivity; severe underlying disease, immunodeficiency, or craniofacial/genetic disorders; active infection; treatment non-adherence; Grade 3–4 tonsils; or previous adenoid/tonsil surgery

Intervention groups

1. Combination Nasal Spray Group(azemix f) 2. Fluticasone Nasal Spray Group 3. Azelastine Nasal Spray Group

Main outcome variables

Change in the severity of clinical symptoms and change in adenoid size after 12 weeks of treatment, assessed by nasal endoscopy and lateral neck radiography.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200718048126N2**
Registration date: **2026-10-01, 1405/07/09**
Registration timing: **prospective**

Last update: **2026-10-01, 1405/07/09**
Update count: **0**

Registration date

2026-10-01, 1405/07/09

Registrant information

Name

Maryam Akbari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-07, 1405/07/15

Expected recruitment end date

2027-03-21, 1406/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Combined Spray (Fluticasone + Azelastine) Spray versus Single-Agent Use of Fluticasone Spray and Azelastine Spray in Improving Clinical Symptoms and Adenoid Size in Children with Adenoid Hypertrophy - Clinical Trial

Public title

Comparison of the Effectiveness of Combined Fluticasone and Azelastine Spray with Fluticasone and Azelastine Single-Agent Sprays in Children with Adenoid Hypertrophy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 6–12 years with a diagnosis of adenoid hypertrophy, confirmed by clinical symptoms and physical examination, nasal endoscopy, and lateral cephalometric radiography, who present to Amiralmomenin Educational and Medical Center in Rasht, will be enrolled in the study. These children must have experienced at least one of the following clinical symptoms for a minimum of 3 months: chronic nasal obstruction, nocturnal snoring, mouth breathing, rhinorrhea, cough, or hyponasal speech. The palatine tonsils must be normal in size or classified as Grade 1–2. The children must not have an indication for tonsillectomy due to chronic tonsillar inflammation.

Exclusion criteria:

Children who have used systemic or topical corticosteroids, decongestants, or antihistamines within the previous 2 weeks Children with a known hypersensitivity to fluticasone or azelastine. Children with severe underlying medical conditions, such as uncontrolled asthma, cardiac or hepatic diseases, immunodeficiency disorders, craniofacial anomalies including cleft lip and palate, genetic disorders (such as Down syndrome), or neurological disorders. Children with an active respiratory or sinus infection requiring antibiotic treatment, or those who use other antiallergic medications or corticosteroids during the study. Children who do not adhere to the treatment protocol. Children with Grade 3 or 4 palatine tonsils, a history of peritonsillar abscess occurring more than twice a year, or an upper respiratory tract infection within the previous 2 weeks. Children with a history of previous adenoid surgery or tonsillectomy.

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed using blocks of six and sealed envelopes. After the patients are admitted to the hospital, undergo an initial evaluation, and meet the inclusion criteria, the study design will be explained to them and informed consent will be obtained. The patients will then be randomly allocated in a 1:1:1 ratio using PASS 11.0 in blocks of six. For each block, one envelope will be randomly selected from six sealed envelopes containing the group assignments: two envelopes for the fluticasone group, two envelopes for the combination spray group, and two envelopes for the azelastine group. The patients will be assigned to the corresponding treatment groups according to the selected envelope. After completion of the first block or set of six envelopes, another set of six envelopes with the same contents will be prepared and randomly selected. The six-patient blocks will be repeated until the required sample size has been reached and all data have been collected.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the interventions used in this study, blinding of the study participants will not be possible, and the patients and their parents will be aware of the type of medication received. However, the study will be conducted as a single-blind study with respect to outcome assessors and data analyser; accordingly, the assessors will be blinded to the patients' group allocation. After obtaining informed consent and confirming the patient's eligibility, allocation to one of the three study groups will be performed using opaque, non-transparent, sequentially numbered, and sealed envelopes. The designated person responsible for allocation will open the corresponding envelope, and the patient will be assigned to one of the three study groups according to its contents. Information regarding the assigned study group will not be disclosed to the outcome assessors until the completion of outcome assessment.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Guilan University of Medical Sciences

Street address
Namjoo Street – Shahid Sayyadi Street – Opposite 17 Shahrivar Hospital – Vice-Chancellery for Research and Technology of the University

City
rasht

Province
Guilan

Postal code
4144666949

Approval date
2026-04-08, 1405/01/19

Ethics committee reference number
IR.GUMS.REC.1405.015

Health conditions studied

1

Description of health condition studied
Patients with adenoid hypertrophy

ICD-10 code
J35.2

ICD-10 code description
Hypertrophy of adenoids

Primary outcomes

1

Description
Clinical symptom severity of adenoid hypertrophy will be assessed using the Berlucchi criteria at baseline and at weeks 4, 8, and 12 and compared among the three groups. Adenoid size will also be assessed by nasal endoscopy and lateral neck radiography at baseline and at week 12, and changes will be compared among the three

Timepoint
Outcome variables will be assessed at baseline and at weeks 4, 8, and 12

Method of measurement
Outcome variables will be assessed using the Berlucchi criteria, nasal endoscopy, lateral neck radiography, and a quality-of-life questionnaire.

Secondary outcomes

1

Description
Clinical symptom severity of adenoid hypertrophy will be assessed using the Berlucchi criteria at baseline and at weeks 4, 8, and 12 and compared among the three groups. Adenoid size will also be assessed by nasal endoscopy and lateral neck radiography at baseline and at week 12, and changes will be compared among the three

Timepoint
Outcome variables will be assessed at baseline and at weeks 4, 8, and 12

Method of measurement
Outcome variables will be assessed using the Berlucchi criteria, nasal endoscopy, lateral neck radiography, and a quality-of-life questionnaire.

Intervention groups

1

Description
First intervention group: Combination azelastine/fluticasone nasal spray: 137/50 µg per spray; one spray into each nostril twice daily for 12 weeks.

Category
Treatment - Drugs

2

Description
Intervention groupsecond intervention group: Fluticasone nasal spray: 50 µg per spray; one spray into each nostril twice daily for 12 weeks.:

Category
Treatment - Drugs

3

Description
Third intervention group: Azelastine nasal spray: 137 µg per spray; one spray into each nostril twice daily for 12 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amiralmomenin hospital

Full name of responsible person
Maryam Akbari

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Dr. Heshmat Square, 17 Shahrivar Street, Amir Al-Momenin Hospital.

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellery for Research and Technology, Guilan University of Medical Sciences
Full name of responsible person
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Rasht – Namjoo Street – Shahid Sayadati Street – Opposite 17 Shahrivar Hospital – Vice-Chancellery for Research and Technology, University
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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
none
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
Rasht University of Medical Sciences
Full name of responsible person
Maryam Akbari
Position
Associate professor
Latest degree
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Other areas of specialty/work
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Sharing plan

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

Study Protocol
No - There is not a plan to make this available

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

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
Data sharing will be conducted comprehensively and will include all variables mentioned above, rather than being limited solely to the primary outcomes. Following the removal of all direct identifiers (such as names, medical record numbers, and national identification numbers) and in accordance with ethical considerations, these data will be made available to researchers for valid research purposes.

When the data will become available and for how long
Access to the research data and study documentation will commence upon completion of the study and following the publication of the initial findings in a scientific article.

To whom data/document is available
After the end of the study period, the results will be available to the public in the form of articles

Under which criteria data/document could be used
If published as an article

From where data/document is obtainable
ENT Research Center of Guilan University of Medical Sciences

What processes are involved for a request to access data/document
In-person referral or electronic request to the ENT Research Center of Guilan University of Medical Sciences

Comments