Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Efficacy comparison between topical fluticasone combined with azelastine and fluticasone alone on clinical symptoms and radiologic finding in children with adenoid hypertrophy

Protocol summary

Study aim

Comparison of the effect of fluticasone combined with topical azelastine and fluticasone alone on clinical and radiological symptoms in children with hypertrophy

Design

Phase 3 clinical trial with parallel control and intervention groups, double-blind, randomized quadruple block with sealed envelope, on 60 patients

Settings and conduct

Patients 4 to 12 years old and have clinical symptoms of adenoid hypertrophy at the Baqiyatallah Hospital clinic will first undergo a lateral neck XRay , audiometry, and a questionnaire. Then, in a double-blind, four-block with use of sealed envelope, the spray, the method of use, and the follow-up of the trial will be explained based on the selected group. The patient, researcher, and data analyst are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children aged 4 to 12 years with clinical and radiological signs of adenoid hypertrophy, grade 1 and 2 palatine tonsils. Exclusion criteria: Use of antibiotics and nasal sprays in the last month, and palatine tonsils grade 3 and 4. History of adenotonsillectomy, pretonsillar abscess more than twice a year, chronic tonsillitis.

Intervention groups

The intervention group, after evaluation with (clinical symptoms questionnaire, radiography, audiometry), is treated with fluticasone-azelastine spray for 6 weeks, and then the evaluation (clinical symptoms questionnaire, radiography, and audiometry) is repeated, and the drug is discontinued for 6 weeks and re-evaluated (clinical symptoms questionnaire). The control group is the same but treated only with fluticasone spray.

Main outcome variables

Rhinitis; Chronic cough; Mouth breathing; Nasal speech; Snoring; Adenoid to nasopharynx ratio on lateral neck radiography; Tympanometry; ABG; Time to onset of symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241023063479N1**
Registration date: **2025-01-06, 1403/10/17**
Registration timing: **prospective**

Last update: **2025-01-06, 1403/10/17**
Update count: **0**

Registration date

2025-01-06, 1403/10/17

Registrant information

Name

zohreh ajalloueyan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2685 1756

Email address

zohrehajall@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-20, 1403/11/01

Expected recruitment end date

2025-07-06, 1404/04/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy comparison between topical fluticasone combined with azelastine and fluticasone alone on clinical symptoms and radiologic finding in children with adenoid hypertrophy

Public title
Comparison of the effect of fluticasone and fluticasone-azelastine spray on clinical and radiological symptoms of adenoid hypertrophy.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 4 to 12 years Adenoid obstruction of at least 50% of the nasopharynx on lateral neck radiography with one of the symptoms of chronic nasal obstruction consistent with adenoid hypertrophy (mouth breathing, nasal discharge, snoring, chronic cough, nasal speech) Grade one or two palatine tonsils Absence of chronic tonsillitis Not having peritonsillar abscesses more than twice a year No history of previous adenoid surgery or tonsillectomy There are no contraindications to the use of topical corticosteroid in the form of a nasal spray. Patient and parent consent to participate in the study No upper respiratory infection in the past 2 weeks Absence of anatomical sinus abnormalities or diseases, craniofacial abnormalities such as cleft lip and palate, genetic diseases (e.g., Down syndrome), neurological or cardiovascular diseases, history of asthma, hypersensitivity to study drugs No steroid or antibiotic treatment, topical or systemic, in the past 4 weeks
Exclusion criteria:
Grade three or four palatine tonsils Having peritonsillar abscesses more than twice a year Upper respiratory infection in the past 2 weeks History of previous adenoid surgery or tonsillectomy
Age
From **4 years** old to **12 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Quadruple block randomization using sealed envelopes After the patients enter the clinic and after the initial assessment and meeting the conditions for entry into the study, after explaining the design and obtaining consent, one envelope is randomly selected from among the four envelopes whose contents are written (fluticasone group, fluticasone group, fluticasone-azelastine group, fluticasone-azelastine group) and is placed in the control and intervention groups based on it. After completing the first block or set of four envelopes, four other envelopes with the same content are prepared and then randomly selected. The blocks of four are repeated until a final 60 data are collected (15 blocks of four, each block having two control groups and two intervention groups).
Blinding (investigator's opinion)
Double blinded
Blinding description
Participant,Investigator and Data analyser a blind. After the patient's eligibility for the study is confirmed, the data collector selects and opens the sealed envelope and, based on the contents inside the envelope, places the patient in the intervention or control group. The patient will not be informed of the group they are placed in. The data collector is different from the analyst, and after collecting the data, only the information will be given to them as a and b without specifying the control and intervention groups. The researcher is also different from the analyst and data collector, and will not be informed of the control and intervention groups in the selection process and statistical results.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Baqiyatallah University of Medical Sciences
Street address
Sheykh bahayi St, Vanak Sq, Mollasadra St, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۳۵۹۱۶۴۷۱
Approval date
2024-10-12, 1403/07/21
Ethics committee reference number
IR.BMSU.BAQ.REC.1403.151

Health conditions studied

1

Description of health condition studied

Adenoid hypertrophy

ICD-10 code

J35.2

ICD-10 code description

Hypertrophy of adenoids

Primary outcomes

1

Description

Adenoid size

Timepoint

At the beginning of the study (before the start of the intervention), 6 weeks after taking the drug

Method of measurement

Adenoid to choanae size ratio on lateral neck radiograph

2

Description

Nasal speech

Timepoint

At the beginning of the study (before the intervention), 6 weeks after taking the drug, 6 weeks after stopping the drug

Method of measurement

Clinical symptom questionnaire

3

Description

Mouth breathing

Timepoint

At the beginning of the study (before the intervention), 6 weeks after taking the drug, 6 weeks after stopping the drug

Method of measurement

Clinical symptom questionnaire

4

Description

Snoring

Timepoint

At the beginning of the study (before the intervention), 6 weeks after taking the drug, 6 weeks after stopping the drug

Method of measurement

SNORING SCALE SCORE -Cambridge University

5

Description

Chronic cough

Timepoint

At the beginning of the study (before the intervention), 6 weeks after taking the drug, 6 weeks after stopping the drug

Method of measurement

Clinical symptom questionnaire

6

Description

Rhinorrhea

Timepoint

At the beginning of the study (before the intervention), 6 weeks after taking the drug, 6 weeks after stopping the drug

Method of measurement

Clinical symptom questionnaire

7

Description

Air bone gap in audiometry

Timepoint

At the beginning of the study (before the intervention), 6 weeks after taking the drug

Method of measurement

Audiometry

8

Description

Tympanometry

Timepoint

At the beginning of the study (before the start of the intervention), 6 weeks after taking the drug

Method of measurement

Tympanometry

Secondary outcomes

empty

Intervention groups

1

Description

Control group or fluticasone: A group of patients who use fluticasone nasal spray twice a day at a dose of 50ug for 6 weeks. Then clinical symptoms and lateral neck radiography and audiometry are repeated, then the drug is discontinued for 6 weeks and then clinical symptoms are asked.

Category

Treatment - Drugs

2

Description

Intervention group or fluticasone-azelastine:A group of patients who use fluticasone-azelastine nasal spray twice a day at a dose of 137ug/50ug for 6 weeks. Then clinical symptoms and lateral neck radiography and audiometry are repeated, then the medication is discontinued for 6 weeks and then clinical symptoms are asked.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Baqiyatallah hospital
Full name of responsible person
Zohreh Ajalloueyan
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Sheykh bahayi St, Vanak Sq, Mollasadra St
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info@bmsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
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Researchsystem@bmsu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Zohreh Ajalloueyan
Position
Consultant
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
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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