Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Investigation of the effectiveness of using 0.65% sodium chloride nasal spray in children aged 6 to 18 years with allergic rhinitis and asthma

Protocol summary

Study aim

This study aims to assess the effectiveness of 0.65% sodium chloride nasal spray versus placebo on symptoms, quality of life, medication use, and asthma control in children with allergic rhinitis

Design

Two-arm, parallel group, double-blind, randomized controlled trial conducted at a single center with a target sample size of 68 participants. Randomization was performed at the individual level using computer-generated simple randomization, and outcome assessment was blinded

Settings and conduct

This single-center randomized controlled trial will enroll 68 children with allergic rhinitis. Participants will be randomized to intervention or placebo sprays in a double-blind design with participants, providers, investigators, and outcome assessors masked. Ethical approval has been granted and informed consent will be obtained from parents or guardians.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children aged 6–18 years allergic rhinitis (with or without asthma) confirmed by an allergy specialist Written informed consent Exclusion criteria: Presence of chronic heart or lung disease, chronic pneumonia, or immune deficiency Other nasal diseases such as non-allergic rhinitis, nasal polyps, or septal deviation Withdrawal of consent during the study Development of new medical conditions requiring discontinuation Occurrence of adverse events such as bleeding or drug hypersensitivity

Intervention groups

Intervention group: Participants receive 0.65% sodium chloride nasal spray in addition to routine care (cetirizine, montelukast, or seroflo as clinically indicated). Control group: Participants receive placebo nasal spray with identical appearance and packaging in addition to routine care.

Main outcome variables

Primary outcomes are changes in nasal symptom severity (TNSS), quality of life (RQLQ), medication use, and asthma control over 4 weeks

General information

Reason for update

Acronym

SNS-ARAS

IRCT registration information

IRCT registration number: **IRCT20150426021944N6**
Registration date: **2025-09-22, 1404/06/31**
Registration timing: **prospective**

Last update: **2025-09-22, 1404/06/31**
Update count: **0**

Registration date

2025-09-22, 1404/06/31

Registrant information

Name

Hamidreza Houshmand

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2026-04-20, 1405/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effectiveness of using 0.65% sodium chloride nasal spray in children aged 6 to 18 years with allergic rhinitis and asthma

Public title

Studying a Natural Relief for Children with Allergies and Asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 6 to 18 years Diagnosis of moderate to severe allergic rhinitis according to the ARIA 2019 guidelines and an allergist with typical symptoms including sneezing, clear nasal discharge, nasal congestion, and nasal itching Diagnosis of moderate to severe asthma based on spirometry (FEV1/FVC ratio less than 60% and ≥12% improvement in FEV1 with an absolute increase of ≥200 ml after salbutamol administration) Written parental consent to participate in the study No diagnosis of cardiac or pulmonary diseases other than asthma, chronic pneumonia, and immunodeficiency No non-allergic nasal congestion such as non-allergic rhinitis, nasal polyps, deviated septum, and concha bullosa

Exclusion criteria:

Disagreement to continue participating in the study Development of new diseases affecting the treatment process during the study Bleeding or other complications during treatment Sensitivity to the medication or any medical condition that requires discontinuation of treatment

Age

From **6 years** old to **18 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, randomization was carried out using a simple randomization method with an equal 1:1 allocation ratio between the intervention group and the control group. The unit of randomization was the individual participant, specifically children aged 6–18 years who met the inclusion criteria. The randomization sequence was generated electronically through Randomization.com, a computer-based tool designed for clinical trials. The sequence was created in advance, with assignments prepared in a simple random list, ensuring that each eligible participant had an equal probability of being allocated to either group. During enrollment, participants were assigned sequentially according to the pre-generated list. This approach ensured a straightforward allocation process, though the document does not specify the use of stratification, blocking, or other pseudorandomization techniques. The study was conducted in a double-blind manner, meaning both participants and outcome assessors were unaware of group assignments, and a placebo spray was used to preserve masking.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this trial, participants were blinded by the use of indistinguishable nasal sprays, with the intervention group receiving 0.65% sodium chloride spray and the control group receiving a placebo spray. The sprays were identical in appearance, packaging, and method of administration, ensuring that participants could not determine their group assignment. Healthcare providers (caregivers delivering the intervention and routine care) were also blinded, since they administered sprays that were identical in form and labeling, and thus could not differentiate between treatment and placebo. The principal investigators and study team responsible for trial oversight remained blinded to allocation throughout participant enrollment and follow-up, thereby preventing any intentional or unintentional bias in patient management or trial conduct. Outcome assessors, who collected symptom scores, quality-of-life measures, and asthma severity indices, were blinded to group allocation, ensuring that clinical assessments and data collection were unbiased. While the data collectors overlapped with outcome assessors and thus remained blinded, the data analysts were not explicitly reported as blinded in the protocol; therefore, it is likely that they had access to group allocation codes during statistical analysis. No Data Safety and Monitoring Board (DSMB) was established for this small investigator-initiated academic study, as DSMBs are typically reserved for large-scale or industry-sponsored trials. Finally, manuscript writers were members of the investigator team and therefore were not independent or blinded at the stage of report preparation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Vice Chancellor for Research, UMSU Central Site, Orjhans Street, Resalat Blvd, Urmia ,Iran

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Province
West Azarbaijan

Postal code
5714783734

Approval date
2025-08-27, 1404/06/05

Ethics committee reference number
IR.UMSU.REC.1404.228

Health conditions studied

1

Description of health condition studied
Allergic rhinitis in children, with or without comorbid asthma

ICD-10 code
J30

ICD-10 code description
Vasomotor and allergic rhinitis

Primary outcomes

1

Description
Change in Total Nasal Symptom Score (TNSS) in children with allergic rhinitis.

Timepoint
Measured at baseline (before intervention) and after 4 weeks of intervention

Method of measurement
Standardized Total Nasal Symptom Score (TNSS) questionnaire

Secondary outcomes

1

Description
Change in asthma severity score

Timepoint
Baseline (before intervention), 2 weeks, and 4 weeks after intervention

Method of measurement
Pediatric Asthma Severity Score, assessed by standardized clinical examination and history (including wheeze, use of accessory respiratory muscles, and expiratory prolongation) using a structured data collection form

Intervention groups

1

Description
Intervention group: Participants receive 0.65% sodium chloride nasal spray (isotonic saline) in addition to routine care (cetirizine, montelukast, or seroflo as clinically indicated). The spray is administered intranasally at the prescribed daily dose for 4 weeks.

Category
Treatment - Drugs

2

Description
Control group: Received routine treatment plus placebo instead of decosalin.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Urmia Motahari Hospital

Full name of responsible person
Fatemeh Seyfi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Hamid Reza Houshmand

Position

Associate Professor

Latest degree

Subspecialist

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

Yes - There is 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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

“Deidentified Individual Participant Data (IPD) set; Study Protocol; Statistical Analysis Plan; Informed Consent Form (template); Data Dictionary.” The IPD will include deidentified baseline characteristics and all outcome measures collected during the trial. The protocol and statistical analysis plan will be the final versions used for

the study. The informed consent form will be the final approved template (with personal/contact fields redacted). The data dictionary will define each variable, units, coding, and allowable ranges.

When the data will become available and for how long

Beginning 6 months after publication of the primary results and continuing for 5 years thereafter.

To whom data/document is available

Qualified researchers from academic or non-profit institutions with a methodologically sound proposal. Industry researchers may also apply if the request aligns with the consent and ethical approvals.

Under which criteria data/document could be used

Access will be granted for analyses addressing the research questions described in an approved proposal, contingent on: (1) submission of a brief protocol and analysis plan, (2) evidence of local ethics approval or exemption, (3) signing a Data Use Agreement prohibiting re-identification, unauthorized sharing, and commercial use, and (4) approval by the Data Access Committee (Principal Investigator plus two co-investigators). Data will be provided deidentified via a secure, time-limited link.

From where data/document is obtainable

Dr.Hamidreza Houshmand

What processes are involved for a request to access data/document

Submit a request including a one-page proposal (objectives, variables requested, analysis plan), proof of ethics approval/exemption, and a signed confidentiality statement. The Data Access Committee will review within ~30 days. If approved, a Data Use Agreement will be issued for signature; upon execution, deidentified data and documents will be shared via secure transfer within ~10 business days.

Comments