Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effectiveness of adjuvant therapy with Vitamin D3 in children with allergic rhinitis

Protocol summary

Study aim
Evaluation of the Efficacy of Adjunctive Vitamin D3 Therapy in Children with Allergic Rhinitis

Design
A phase 3 randomized controlled trial with parallel groups, single-blind design, conducted on 48 patients. Randomization will be performed using Microsoft Excel.

Settings and conduct
This study is a single-blind randomized clinical trial with primary outcomes of TNSS and RQLQ, including a total of 48 participants under 18 years old with moderate to severe allergic rhinitis, recruited from the allergy clinics of Urmia University of Medical Sciences. Standard therapy, consisting of an oral antihistamine (cetirizine), an oral leukotriene receptor antagonist (montelukast), and a nasal corticosteroid (mometasone), will be administered to both groups. Oral vitamin D3 pearls (1000 IU every other day) will be given exclusively to the intervention group in addition to the standard therapy. Patient information forms will be completed at baseline (week 0) and at 8 weeks, including demographic data (age, sex, weight, height, mode of delivery, type of infant feeding, rural/urban residence), which will be compared after data collection. Since the study is single-blind, participants will not be aware of their assigned intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children with allergic rhinitis. Exclusion criteria: Presence of risk to the participant, non-allergic rhinitis, or lack of consent to participate in the study.

Intervention groups
Oral vitamin D3 pearls (1000 IU every other day)

Main outcome variables
Reduction of symptoms, improvement in sleep quality, improvement in academic performance, relief of fatigue, and alleviation of depressive symptoms.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150426021944N7**
Registration date: **2025-10-19, 1404/07/27**
Registration timing: **prospective**

Last update: **2025-10-19, 1404/07/27**
Update count: **0**

Registration date
2025-10-19, 1404/07/27

Registrant information

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Hamidreza Houshmand

Name of organization / entity
Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-23, 1404/08/01

Expected recruitment end date
2026-03-20, 1404/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of adjuvant therapy with Vitamin D3 in children with allergic rhinitis

Public title
Evaluation of the effectiveness of adjuvant therapy with Vitamin D3 in children with allergic rhinitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children under 18 years with allergic rhinitis Presence of allergic rhinitis symptoms (rhinorrhea, sneezing, nasal congestion, and itching of nose, eyes, throat, and palate) Moderate severity (symptoms ≥4 days per week or ≥4 consecutive weeks) or severe (symptoms with impaired sleep, school, or daily activities) according to ARIA criteria Written informed consent from parents or legal guardians for participation in the study

Exclusion criteria:
Non-allergic rhinitis Anatomical or obstructive nasal disorders (polyp, tumor, bacterial sinusitis, adenoid or tonsillar hypertrophy) Presence of asthma Presence of serious diseases such as kidney disease Use of potent systemic drugs such as oral corticosteroids Use of Vitamin D3 during the past six months Use of medications affecting serum Vitamin D levels (such as antiepileptics, metformin, diuretics, calcium channel blockers, etc) Intolerance to Vitamin D3 pearls Unwillingness to participate in the study or lack of informed consent from parents or legal guardians

Age
To **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
At the beginning, all participants will be evaluated based on their symptoms using the Total Nasal Symptom Score (TNSS), which assesses sneezing, nasal congestion, rhinorrhea, and itching. Participants will then be randomly assigned, using Excel software, into two groups: 24 in the intervention group (standard therapy plus oral Vitamin D3) and 24 in the control group (standard therapy alone), after obtaining written informed consent and the ethics approval code.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, only the participants will be blinded to the type of intervention they receive. Patients will not know whether they are receiving Vitamin D3 in addition to standard therapy or standard therapy alone. The principal investigators and treating physicians will be aware of the intervention due to the nature of the medications. Data collectors and outcome assessors will be blinded to the group assignments in order to minimize bias in the evaluation of outcomes.

Placebo
Not used

Assignment
Parallel

Other design features
Standard therapy, consisting of an oral antihistamine (cetirizine), an oral leukotriene receptor antagonist (montelukast), and a nasal corticosteroid (mometasone), will be administered to both groups. Oral vitamin D3 pearls (1000 IU every other day) will be given exclusively to the intervention group in addition to the standard therapy. Since a prophylactic dose of oral vitamin D3 (1000 IU every other day) is used, no significant increase in blood levels or toxicity is expected.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences, West Azerbaijan

Street address
Vice President of Research and Technology Development, West Azarbaijan University of Medical Sciences and Medical Services, Urmia, Jihad St

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

Ethics committee reference number
IR.UMSU.REC.1404.188

Health conditions studied

1

Description of health condition studied
Allergic rhinitis

ICD-10 code
J30

ICD-10 code description
Vasomotor and allergic rhinitis

Primary outcomes

1

Description

Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) score

Timepoint

Patient information forms will be completed at the baseline visit (week 0) and at 8 weeks, and the collected data will be compared thereafter.

Method of measurement

Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ)

2

Description

Total Nasal Symptom Score (TNSS)

Timepoint

Patient information forms will be completed at the baseline visit (week 0) and at 8 weeks, and the collected data will be compared thereafter.

Method of measurement

Total Nasal Symptom Score (TNSS) questionnaire

Secondary outcomes

1

Description

Improvement in sleep quality

Timepoint

Patient information forms will be completed at the baseline visit (week 0) and at 8 weeks, and the collected data will be compared thereafter.

Method of measurement

Self-reported

2

Description

Improvement in academic performance

Timepoint

Patient information forms will be completed at the baseline visit (week 0) and at 8 weeks, and the collected data will be compared thereafter.

Method of measurement

Self-reported

3

Description

Relief of fatigue

Timepoint

Patient information forms will be completed at the baseline visit (week 0) and at 8 weeks, and the collected data will be compared thereafter.

Method of measurement

Self-reported

4

Description

Alleviation of depressive symptoms

Timepoint

Patient information forms will be completed at the baseline visit (week 0) and at 8 weeks, and the collected data will be compared thereafter.

Method of measurement

Self-reported

Intervention groups

1

Description

Intervention group: Standard treatment consisted of an oral antihistamine (cetirizine), an oral leukotriene receptor antagonist (montelukast), and a nasal corticosteroid (mometasone) + Recipients of oral vitamin D3 pearls (1000 IU every other day for 8 weeks)

Category

Treatment - Drugs

2

Description

Control group: Standard treatment consisted of an oral antihistamine (cetirizine), an oral leukotriene receptor antagonist (montelukast), and a nasal corticosteroid (mometasone).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Allergi clinic of Urmia university of medical sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
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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