Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effectiveness of implementing clinical guidelines on respiratory function in school-age children with allergic rhinitis

Protocol summary

Study aim
Determining the effect of implementing clinical guidelines on respiratory function in school-age children with allergic rhinitis

Design
A randomized, controlled clinical trial was conducted. Med Calc statistical software was used for randomization.

Settings and conduct
The training of this guide will be held for 8 sessions in university-affiliated teaching hospitals. Approximately 12 children will participate in each session. During this period, patients in the control group will only receive care related to the care of children with AR disease. The intervention group will receive the necessary training based on clinical guidelines.

Participants/Inclusion and exclusion criteria
1-School-aged children (6-12 years) 2-Confirmation of seasonal AR disease diagnosis by a specialist physician based on clinical criteria 3-Absence of other chronic respiratory diseases such as severe asthma, chronic bronchitis, or active respiratory infections 4-Children with stable general health and no acute or chronic diseases affecting the study results Exclusion criteria 1- History of hypersensitivity or severe adverse reactions to treatments recommended in the clinical guidelines 2-Unwillingness or inability of the family or child to adhere to study instructions or attend follow-up sessions 3-Withdrawal of the family or child from continuing to participate in the study or unwillingness to provide informed consent. 4- Presence of severe psychological or behavioral problems in the child that may make it difficult to cooperate in the study.

Intervention groups
Patients in the intervention group will undergo an educational intervention guided by the care of school-age children with AR based on the EUFOREA guidelines.

Main outcome variables
1-Forced vital capacity (FVC) 2-Forced expiratory volume in the first second (FVC) 3-Peak expiratory flow 4-Nasal congestion 5-Runny nose 6-Sneezing 7-Itching

General information

Reason for update

Acronym
TEICGRF

IRCT registration information
IRCT registration number: **IRCT20260607069683N1**
Registration date: **2026-09-13, 1405/06/22**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-13, 1405/06/22**
Update count: **0**

Registration date
2026-09-13, 1405/06/22

Registrant information

Name
Mohammad Absalan

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-08-23, 1405/06/01

Expected recruitment end date
2026-10-21, 1405/07/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of implementing clinical guidelines on respiratory function in school-age children with allergic rhinitis

Public title
The effectiveness of implementing clinical guidelines on respiratory function in school-age children

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
School-age children (6 to 12 years old) Confirmation of the diagnosis of seasonal allergic rhinitis (AR) by a specialist physician based on clinical criteria Absence of other chronic respiratory diseases such as severe asthma, chronic bronchitis, or active respiratory infections Obtaining informed consent from the child's parents or legal guardian and, where possible, the child's assent Children in stable general health, without acute or chronic diseases that could affect the study results

Exclusion criteria:
History of hypersensitivity or severe adverse reactions to treatments recommended in the clinical guideline Unwillingness or inability of the family or child to adhere to study instructions or participate in follow-up sessions Family or child's refusal to continue participating in the study or unwillingness to provide informed consent. The presence of severe psychological or behavioral problems in the child that may make it difficult to cooperate in the study.

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Random sampling process and sample size, which will be allocated to two control groups (36 people) and intervention (36 people) based on simple random method. Randomization unit: individual, randomization tool: random number table, to create a random sequence with the help of a random number table and by a statistical consultant, patients were randomly assigned one of the even and odd codes. Patients who were assigned even numbers were placed in the first group and patients with odd codes were placed in the second group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of AHWAZ University of Medical Sciences

Street address
University of Medical Sciences

City
AHWAZ

Province
Khouzestan

Postal code
1579461357

Approval date
2026-01-11, 1404/10/21

Ethics committee reference number
IR.AJUMS.REC.1404.546

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
Forced vital capacity (FVC): The amount of air that can be exhaled from the lungs after the deepest possible breath

Timepoint
Before, immediately and after the intervention

Method of measurement
Pulmonary function assessment using spirometry

2

Description
Forced expiratory volume in the first second (FVC): The volume of air exhaled in the first second during forced expiration after maximal inspiration

Timepoint
Before, immediately and after the intervention

Method of measurement
Pulmonary function assessment using spirometry

3

Description
Nasal congestion
Timepoint
Before, immediately and after the intervention
Method of measurement
Based on the VSA scale, a score of zero indicates no nasal congestion, a score of 1 to 3 indicates mild nasal congestion.

4

Description
Nasal congestion
Timepoint
Before, immediately and after the intervention
Method of measurement
Based on the VSA scale, a score of zero indicates no nasal congestion, a score of 1 to 3 indicates mild nasal congestion.

Secondary outcomes

1

Description
Assessing symptoms of allergic rhinitis
Timepoint
Before, immediately, and after the intervention
Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group: After recording demographic information, patients in the intervention group will undergo a simple educational intervention guide for the care of school-age children with AR based on the EUFOREA guidelines in addition to routine care. The training of this guide will be held for 8 sessions in teaching hospitals affiliated with Ahvaz Jundishapur University of Medical Sciences. The educational sessions will be held in a room in teaching hospitals affiliated with Ahvaz Jundishapur University of Medical Sciences. About 12 children will participate in each session. During this period, patients in the control group will only receive routine care related to the care of children with AR. As explained in the previous sections, the educational intervention protocol based on the EUFOREA clinical guidelines will be held in 8 sessions. The topic of the first session will be familiarization with allergic rhinitis. In the first session, children will be familiarized with the concept of allergic rhinitis, its common symptoms including runny nose, sneezing, itching, and nasal congestion, and its difference from colds or other respiratory diseases. This session will explain the importance of early diagnosis and proper treatment of the disease, the role of genetic and environmental factors, and the impact of untreated rhinitis on a child's academic performance and quality of life. The topic of the second session will be recognizing allergens and effective environmental factors. The second session will focus on recognizing common triggers and allergens such as dust mites, mold, pets, pollen, air pollution, and cigarette smoke. In this session, children will be taught how these factors can aggravate symptoms and what steps can be taken to identify and control them in the living environment. The topic of the third session will be the principles of prevention and avoidance of allergens. The third session will teach practical strategies for reducing exposure to allergens. Emphasis will be placed on things such as properly ventilating the child's room, washing sheets regularly with hot water, using hypoallergenic covers for pillows and mattresses, limiting contact with pets, and using masks during pollen seasons. The topic of the fourth session will be teaching non-pharmacological treatments. During the fourth session, non-pharmacological measures in the control of allergic rhinitis will be taught. Participants will be introduced to the importance of nasal irrigation with saline solution and will be given practical training on how to do it correctly. In this session, how to prepare homemade saline solution and the appropriate frequency of irrigation will be explained. The topic of the fifth session will be drug therapy training based on the EUFOREA guidelines. In this session, children will be taught proper drug therapy. Participants will be introduced to the types of drugs used in allergic rhinitis (antihistamines, corticosteroid sprays, and combination drugs) and the role of each in controlling symptoms. The correct use of nasal spray will be practiced practically. The topic of the sixth session will be introduction to specific immunotherapy. In this session, the concept of immunotherapy and its role in the long-term treatment of allergic rhinitis will be taught. Participants will be introduced to the two main immunotherapy methods (subcutaneous and sublingual), the duration of treatment, its benefits in reducing the severity of symptoms and preventing asthma. The topic of the seventh session will be training in symptom monitoring and self-assessment. The seventh session will focus on promoting self-care. In this session, how to assess symptoms using a visual analog scale (VAS) or Emoji-VAS will be taught so that children can record the severity of their symptoms on a daily or weekly basis. The topic of the eighth session will be review, summary and final evaluation. In the last session, the content of the training of the previous seven sessions will be reviewed and the extent of learning and behavior change of the participants will be assessed. Key points related to prevention, drug therapy, nasal irrigation and allergen avoidance were reviewed again. Immediately after the intervention, the VAS scale and the patient's clinical status form will be collected by the researcher using spirometry. After 30 days, the parameters related to the study objectives will be collected again by the researcher in both the control and intervention groups using the

same patient clinical status form using spirometry and visual analog scale (VAS).

Category
Lifestyle

2

Description
Control group: They are not given any training.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Abozar Hospital

Full name of responsible person
Mohammad Absalan

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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?
No

Title of funding source
Jondishapour University

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
Ahvaz University of Medical Sciences

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Mohammad Absalan

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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