# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Investigation of the Effect of Plantago Syrup on the Severity of Allergic Rhinitis Symptoms in Patients Referring to Imam Reza (PBUH) Hospital Clinic: A Triple-Blind Clinical Trial

## Protocol summary

**Study aim**

To determine the effect of Plantago major syrup on the severity of allergic rhinitis symptoms in patients referred to the clinic of Imam Reza Hospital.

**Design**

A randomized, triple-blind, placebo-controlled, parallel-group, phase 3 clinical trial on 68 patients (34 in each group) with mild to moderate allergic rhinitis. Randomization method: Permuted block randomization

**Settings and conduct**

Study setting: Imam Reza Hospital clinic Procedure: After obtaining informed consent and completing the SNOT-22 questionnaire (baseline score) Intervention duration: 7 days At the end of day 7, the SNOT-22 questionnaire is completed again. Medication adherence is assessed by counting the remaining medication (consumption of less than 80% = exclusion from analysis). Triple-blind: patient, physician/outcome assessor, and statistical analyst are unaware of group allocation. The syrups are identical in appearance and taste and are labeled with codes. The allocation key is kept by an individual who has no contact with patients.

**Participants/Inclusion and exclusion criteria**

Patients with mild to moderate allergic rhinitis referred to the clinic of Imam Reza Hospital. Inclusion Criteria: Age range between 15 and 65 years Providing written informed consent to participate in the study Exclusion Criteria (Non-inclusion): Pregnancy or breastfeeding Use of corticosteroids or immunosuppressive drugs Concurrent respiratory diseases (e.g., uncontrolled asthma, acute respiratory infection) Immunodeficiency disorders Use of other herbal medicines History of allergy to Plantago major or its components

**Intervention groups**

Intervention group: Plantago syrup 30 cc/day (3 doses of 10 cc) + Cetirizine 10 mg Control group: Placebo syrup 30 cc/day (3 doses of 10 cc) + Cetirizine 10 mg

**Main outcome variables**

Severity of Allergic Rhinitis Symptoms

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20150902023864N5**
Registration date: **2026-09-12, 1405/06/21**
Registration timing: **prospective**

Last update: **2026-09-12, 1405/06/21**
Update count: **0**

**Registration date**

2026-09-12, 1405/06/21

**Registrant information**

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**Recruitment status**

**recruiting**

**Funding source**

**Expected recruitment start date**

2026-09-23, 1405/07/01

**Expected recruitment end date**

2028-09-22, 1407/07/01

**Actual recruitment start date**

empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Investigation of the Effect of Plantago Syrup on the Severity of Allergic Rhinitis Symptoms in Patients Referring to Imam Reza (PBUH) Hospital Clinic: A Triple-Blind Clinical Trial

**Public title**
Investigating the Effect of Plantago Syrup on Reducing Allergy Symptoms in Patients Referred to Imam Reza Hospital
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Having mild to moderate allergic rhinitis (diagnosed by a specialist physician) Providing written informed consent to participate in the study
**Exclusion criteria:**
Pregnancy or breastfeeding Use of corticosteroids or immunosuppressive drugs Concurrent respiratory diseases (e.g., uncontrolled asthma, acute respiratory infection) Immunodeficiency disorders Use of other herbal medicines History of allergy to Plantago major or its components
**Age**
From **15 years** old to **65 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **68**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
After identifying eligible patients and obtaining informed consent, patients are allocated to two equal groups using the Permuted Block Randomization method. In this method, using computer software, random numbers are generated in blocks of a fixed size (e.g., blocks of 4). In each block, an equal number of individuals are assigned to the intervention and control groups (e.g., 2 in the intervention group and 2 in the control group). The order of assignment within each block is determined randomly, and patients are allocated to one of the two groups based on their order of entry and the generated codes. This method ensures that the sample sizes of the two groups remain balanced throughout the study. The allocation list (random sequence) is prepared and maintained by an individual who has no direct contact with the patients (the same person responsible for labeling the medications) and remains confidential until the end of the study and the completion of the statistical analysis.
**Blinding (investigator's opinion)**
Triple blinded
**Blinding description**
1. Blinding of Participants (Patients): The Plantago syrup (intervention group) and placebo syrup (control group) are prepared to be completely identical in terms of appearance, color, odor, taste, consistency, and packaging. Since the main syrup (Barashan) contains honey, to eliminate the taste effect of honey and prevent patients from identifying the drug, the placebo is also sweetened with honey. Therefore, the patient is unaware of the type of syrup they are receiving. 2. Blinding of Clinical Caregivers, Researchers in Contact with Patients, and Outcome Assessors: The treating physician who examines the patient, confirms the diagnosis of allergic rhinitis, records symptoms, and completes the SNOT-22 questionnaire is unaware of the type of syrup the patient is taking. Other research team members who are in contact with patients (including those responsible for recording symptom severity) are also unaware of patient group allocation. These individuals only see the patient's unique code and have no information about which group (intervention or control) the patient belongs to. 3. Blinding of the Data Analyst: The individual performing the statistical analysis will remain unaware of the group codes and treatment types until the initial analysis is fully completed. 4. Implementation of Blinding Procedures: All syrup packages (both Plantago and placebo) are labeled with coded labels containing only the patient identification code, with no indication of drug type or treatment group. The allocation list (decryption key) is kept by a member of the research team who has no direct contact with patients (the same person who initially placed the randomized labels on the packages). This individual is responsible for maintaining the code list and will perform decoding only in the following cases: After completion of data collection and finalization of the initial statistical analysis In necessary situations, such as the occurrence of an unexpected adverse event that requires knowledge of the treatment type 5. Standardization of Procedures: Prior to the start of the study, the approach to patients at all stages of the study (including initial and final visits) is coordinated and standardized in internal meetings to ensure uniform performance among all team members and to minimize potential bias.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Research Ethics Committees of North Khorasan University of Medical Sciences
**Street address**
Shahriar
**City**
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**Province**
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**Postal code**
9417694765
**Approval date**
2026-08-23, 1405/06/01
**Ethics committee reference number**
IR.NKUMS.REC.1405.086

## Health conditions studied

**1**

**Description of health condition studied**
Allergic Rhinitis
**ICD-10 code**
J30.9
**ICD-10 code description**
Allergic rhinitis, unspecified

## Primary outcomes

**1**

**Description**
Severity of Allergic Rhinitis Symptoms
**Timepoint**
Day 0, Day 7
**Method of measurement**
SNOT-22 Questionnaire

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Oral consumption of Plantago syrup for 7 days, along with standard baseline treatment (Cetirizine 10 mg tablet)
**Category**
Treatment - Drugs

**2**

**Description**
Control group: Placebo for 7 days along with standard baseline treatment (Cetirizine 10 mg tablet)
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Imam Reza Clininc
**Full name of responsible person**
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## Sponsors / Funding sources

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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**
Bojnourd 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**

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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**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The primary outcome will be shared.

**When the data will become available and for how long**

Following publication of the results

**To whom data/document is available**

researchers

**Under which criteria data/document could be used**

The data will be accessible for analysis and further investigations. Requests should be submitted via correspondence with the principal investigator.

**From where data/document is obtainable**

email or letter to the PI

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

After obtaining approval from the Vice-Chancellor for Research and Technology of the university, the data will be sent.

**Comments**