

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The effect of nasal spray based on herbal extracts (traditional Persian medicine product) compared to placebo on the symptoms of patients with allergic rhinitis

Protocol summary

Study aim

Determination of the effect of Nasal spray based of herbal extracts(An Iranian Traditional Medicine product) on treatment of allergic rhinitis

Design

Clinical trial with control group, with parallel groups, triple-blind, randomized, phase 2-3 on 76 patients. Permutation blocks are used for randomization.

Settings and conduct

The patients referred to the Iranian Medicine Clinic of Imam Reza (AS) Hospital who suffer from allergic rhinitis were selected. In patients who did not receive treatment for allergic rhinitis for at least one week, the rhinitis-control-assessment-test(RCAT) and Total Nasal Symptom Score(TNSS) questionnaires were completed and then three weeks of treatment was performed. The TNSS questionnaire is completed again. For relapses, the RCAT questionnaire will be completed one week after the end of treatment.

Participants/Inclusion and exclusion criteria

All patients 18 years to 70 years old that according to the Allergic Rhinitis and its Impact on Asthma(ARIA) guideline and diagnosis of a Clinical Immunologist and a Positive Perik Test have allergic rhinitis. No entry criteria: Diffused Nasal Polyps; Pregnancy; history of allergy to Coriander or Bitter orange; Asthma; systemic inflammatory diseases; using antihistamines during the last week before the beginning of the study; using Corticosteroids during the last 2 weeks before the beginning of the study; Lack of consent from the patient to stay in the study for any reason.

Intervention groups

In the intervention group, nasal spray is given in 2 puffs every 8 hours for 3 weeks In the control group, placebo nasal spray is given in 2 puffs every 8 hours for 3 weeks

Main outcome variables

Sneezing, Rhinorrhea, Nasal Congestion, Itchy nose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220517054885N1**

Registration date: **2022-10-02, 1401/07/10**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-02, 1401/07/10**

Update count: **0**

Registration date

2022-10-02, 1401/07/10

Registrant information

Name

Alieh Farabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

farabia971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-06-19, 1402/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nasal spray based on herbal extracts (traditional Persian medicine product) compared to placebo on the symptoms of patients with allergic rhinitis

Public title

Investigation of the effect of herbal nasal spray (Iranian Traditional Medicine product) on treatment of allergic rhinitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients 18 years to 70 years old that according to the ARIA guideline and diagnosis of a clinical Immunologist have allergic rhinitis

Exclusion criteria:

Diffused Nasal Polyps Pregnancy History of allergy to Coriander or Bitter orange Asthmatic patients Systemic inflammatory diseases Using antihistamines during the last week before the beginning of the study Using inhaled corticosteroids during the last 2 weeks before the beginning of the study

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of patients: drug and placebo in the same appearance and package are randomly given to patients in two groups A and B. Randomization of the clinical caregiver: Blocking using permutation block method using the site <https://www.sealedenvelope.com> with the explanation that each of the blocks has 4 members and the shape of the blocks is as follows: [AABB], [ABAB], [ABBA], [BABA], [BBAA], [BAAB] The above-mentioned site randomly selects seventeen blocks from blocks of four, so that finally 76 patients are included in the study. Randomization of the researcher: The researcher analyzes the patients in two groups A and B.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Azadi Square, Faculty of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran

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Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2022-08-16, 1401/05/25

Ethics committee reference number

IR.MUMS.REC.1401.159

Health conditions studied**1****Description of health condition studied**

Allergic Rhinitis

ICD-10 code

J30. 9 - A

ICD-10 code description

Allergic rhinitis, unspecified

Primary outcomes**1****Description**

Nasal obstruction

Timepoint

Baseline and 3 weeks after intervention

Method of measurement

Total Nasal Symptom Score questionnaire

2**Description**

Itching/Sneezing

Timepoint

Baseline and 3 weeks after intervention

Method of measurement

Total Nasal Symptom Score questionnaire

3

Description

Rhinorrhea

Timepoint

Baseline and 3 weeks after intervention

Method of measurement

Total Nasal Symptom Score questionnaire

Secondary outcomes

1

Description

symptom recurrence rate

Timepoint

Baseline and one week after the end of intervention

Method of measurement

Rhinitis Control Assessment Test (RCAT) questionnaire

Intervention groups

1

Description

Intervention group: receiving herbal nasal spray made by researchers in the pharmaceutical laboratory of the school of Persian and Complementary medicine of Mashhad University of Medical Sciences containing 1% coriander seed hydroalcoholic extract, 0.5% bitter orange essential oil , 1% pectin, tween and glycerin in the necessary amount; with the order of 2 puffs every 8 hours inside each nasal cavity for 3 weeks

Category

Treatment - Drugs

2

Description

Control group: receiving a placebo nasal spray made by researchers in the pharmaceutical laboratory of the school of Persian and Complementary medicine of Mashhad University of Medical Sciences containing 1% pectin, tween, and glycerin in the necessary amount and allowed edible color with the order of 2 puffs every 8 hours inside each nasal cavity for 3 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Imam Reza hospital

Full name of responsible person

Dr Alieh Farabi

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Aliieh Farabi

Position

PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

After the end of the research, the results will be published in the form of an original article in an international journal and will be available to other researchers. Access to the raw data collected in this study will be possible after obtaining permission from the principal investigators and the corresponding author. Research use in the form of publishing a new article from the data in this study requires written permission from the researchers of the current study.

When the data will become available and for how long

From the time of publication of the article until one year later

To whom data/document is available

Academic researchers by request from the corresponding author

Under which criteria data/document could be used

Access to the raw data collected in this study will be

possible after obtaining permission from the lead researchers and the responsible author. Research use in the form of publishing a new article of the data in this study requires the written permission of the researchers of current study.

From where data/document is obtainable

Applicants can communicate with the corresponding author via email at farabia971@mums.ac.ir.

What processes are involved for a request to access

data/document

An email containing the introduction of the requester and the explanation of the reason for the request and the description of possible uses will be sent to the corresponding author. If accepted by the corresponding author, the requested information will be sent to the requester via email.

Comments