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-tes(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 Possitive 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

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Iran (Islamic Republic of)

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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

City
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
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Mashhad University of Medical Sciences
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
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Alieh Farabi
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Person responsible for updating data

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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