Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation the effect of propolis on clinical manifestations and Specific IgE levels against Salsola in Perennial allergic rhinitis patients

Protocol summary

Study aim
Comparison of IgE level changes against Salsaula, and clinical manifestations following prescription of Propolis in patients with permanent allergic rhinitis

Design
A clinical trial with the control group, with parallel groups, Triple blinded, and simple randomized, was performed on 44 patients. The random number table was used for randomization.

Settings and conduct
In this study, 44 patients with persistent allergic rhinitis were divided into two groups of intervention and control by simple randomization. In the intervention group, patients receive common treatments and propolis at a dose of 200 mg daily. In the control group, patients receive conventional and placebo treatments daily. The duration of the intervention is six months. Before and six months after the intervention, five ccs of blood is taken from patients to measure the level of specific IgE against Salsola kali allergen, and two questionnaires miniRQLQ and SNOT22, which are related to the quality of life and disease severity, respectively, are completed.

Participants/Inclusion and exclusion criteria
Inclusion criteria are permanent allergic rhinitis, ages between 5-50 years old, living in Mashhad and surrounding cities, a positive skin test with air allergens, and cooperation. Exclusion criteria are a history of autoimmune disease, systemic corticosteroids or pregnancy immunosuppressive drugs, immunodeficiency, allergic asthma, malnutrition, and consumption of antibiotics.

Intervention groups
Intervention group: Patients with persistent allergic rhinitis receive common treatments and 200 mg propolis daily. Control group: Patients with permanent allergic rhinitis receive common placebo treatments daily. The duration of the intervention is six months.

Main outcome variables
The level of specific IgE against Salsola kali allergen

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150716023235N17**
Registration date: **2021-10-10, 1400/07/18**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-10, 1400/07/18**
Update count: **0**

Registration date
2021-10-10, 1400/07/18

Registrant information

Name
Farahzad Jabbari Azad

Name of organization / entity
Allergy Research Center, Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-20, 1400/03/30

Expected recruitment end date
2022-04-09, 1401/01/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation the effect of propolis on clinical manifestations and Specific IgE levels against Salsola in Perennial allergic rhinitis patients

Public title
propolis effects on allergic rhinitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Perennial Allergic Rhinitis Ages between 5-50 years old Living in Mashhad and around cities Positive skin prick test with aeroallergens Cooperation
Exclusion criteria:
Autoimmune disease history Use of systemic corticosteroid or immunosuppressive drugs Pregnancy Immunosuppressive patients Allergic Asthma patients Malnutrition patients Use of antibiotics
Age
From **5 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **15**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants are randomly divided into two groups using a random number table. Individuals who receive the odd number enter the intervention group, and people with even numbers are placed in the control group.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this triple-blind study, patients, investigator, and data analyser were not aware of the type of intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad University of Medical Sciences
Street address
Ghoreishi building Ethics Committee of Mashahd University of Medical Science
City
Mashhad
Province
Razavi Khorasan
Postal code
9175711111
Approval date
2021-06-01, 1400/03/11
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1400.258

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
Specific IgE
Timepoint
Before and after intervention
Method of measurement
Eliza

2

Description
Quality of life
Timepoint
Before and after intervention
Method of measurement
miniRQLQ questionnaire

3

Description
Severity of disease
Timepoint
Before and after intervention
Method of measurement
SNOT22 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, in addition to the usual treatments, 200 mg of propolis is administered daily for 4 months.
Category
Treatment - Drugs

2

Description
Control group: In Control group, in addition to the usual treatments, placebo is administered daily for 4 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Farahzad Jabbari-Azad
Street address
Ghaem hospital, Ahmad Abad Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Mohsen Tafaghodi
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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
Farahzad Jabbari-Azad
Position
Professor
Latest degree
Medical doctor
Other areas of specialty/work
Immunology
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Person responsible for updating data

Contact
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Negar Khalighi
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Subspeciality
Latest degree
Specialist
Other areas of specialty/work
Allergy and Immunology
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Allergy and clinical immunology ward, Ghaem Hospital, Ahmad Abad Boulevard
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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
Not applicable