

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 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 Salsola, 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)

##### Phone

+98 51 1801 2770

##### Email address

jabbarif@mums.ac.ir

##### 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 Mashhad 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.

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

91766-9919

#### Phone

+98 51 3801 2298

#### Email

Jabbarif@mums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Mohsen Tafaghodi

#### Street address

Ghoreishi, Daneshgah Ave, Mashhad

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9175711111

#### Phone

+98 51 3841 2081

#### Email

Ramresearch@mums.ac.ir

#### 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

#### Street address

Allergy Research Center, Ghaem Hospital ,  
Ahmadabad Ave, Mashhad

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

91766-9919

#### Phone

+98 51 3801 2298

#### Email

jabbarif@mums.ac.ir

## Person responsible for scientific 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

#### Street address

Allergy Research Center, Ghaem Hospital ,  
Ahmadabad Ave, Mashhad

#### City

Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
91766-9919  
**Phone**  
051380122898  
**Email**  
jabbarif@mums.ac.ir

Razavi Khorasan  
**Postal code**  
91766-9919  
**Phone**  
+98 51 3801 2829  
**Email**  
khalighin971@mums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Negar Khalighi  
**Position**  
Subspeciality  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Allergy and Immunology  
**Street address**  
Allergy and clinical immunology ward, Ghaem  
Hospital, Ahmad Abad Boulevard  
**City**  
Mashhad  
**Province**

## 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