

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of the Effectiveness of Sublingual Immunotherapy (SLIT) with Routine Medical Treatment and its Effect on Serum Level Changes of IL-25 and IL-33 in Patients with Allergic Rhinitis.

Protocol summary

Study aim

The Purpose of this Study was to compare the Efficacy of Sublingual Immunotherapy with Routine Medical Treatment and its Effects on Serum Levels of Interleukin 25 and 33 in Patients with Allergic Rhinitis.

Design

Parallel, single-blind, randomized clinical trial

Settings and conduct

90 Patients with Allergic Rhinitis that were referred to the manager's clinic of Kashan University of Medical Sciences, Kashan, Iran will be selected in the study. Patients will be divided into two groups. Patients of treatment group will undergo sublingual immunotherapy and patients of control group will use the antihistamine. The severity of the disease and serum levels of interleukin 25 and 33 will be measured at the beginning and at the end of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having Allergic Rhinitis; age over 12 years. Exclusion criteria: Any Respiratory and non-respiratory inflammation such as infection, Recent massive surgery, severe pulmonary or renal disease, alcohol abuse, severe addiction, uncontrolled diabetes, cancer, autoimmune diseases

Intervention groups

Patients will be divided into two groups. So patients in the control group will receive classical allergy treatment (oral Cetirizine 10 mg daily plus nasal Mometasone spray every 12 hours in every nasal cavity), and patients in the treatment group will use sublingual immunotherapy. Sublingual immunotherapy with droplets manufactured by Wolwopharm Company of China has been considered as increasing doses to maintenance levels of two drops of 1000 µg sublingual concentrations.

Main outcome variables

The serum levels of interleukins 25 and 33 and the severity of the disease in patients with Allergic Rhinitis

will be determined and compared at the beginning and at the end of the intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171105037262N1**

Registration date: **2017-12-01, 1396/09/10**

Registration timing: **prospective**

Last update: **2017-12-01, 1396/09/10**

Update count: **0**

Registration date

2017-12-01, 1396/09/10

Registrant information

Name

mohammadhossein pourhanifeh

Name of organization / entity

kashan university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 31 5558 0988

Email address

pourhanifeh-mh@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research assistance of kashan university of medical science

Expected recruitment start date

2017-12-06, 1396/09/15

Expected recruitment end date

2018-06-05, 1397/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Sublingual Immunotherapy(SLIT) with Routine Medical Treatment and it's Effect on Serum Level Changes of IL-25 and IL-33 in Patients with Allergic Rhinitis.

Public title

Sublingual Immunotherapy Effect on Allergic Rhinitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having Allergic Rhinitis Age over 12 years

Exclusion criteria:

Any Respiratory and non-respiratory inflammation such as infection; Recent Massive Surgery; Severe Pulmonary or Renal Disease; Alcohol Abuse; Sever Addiction; Uncontrolled Diabetes; Cancer; Autoimmune diseases

Age

From **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

After specifying the sample size, the first four blocks of A and B letters are formed (6 blocks). Then, each of the blocks is numbered 1 to 6 and based on the selected numbers from random numbers table, we form a sequence of blocks, in which the letters A and B are located, and then randomly one of the letters are considered as the drug group and the other letter as the control group. This method is referred to as "Termuted Blocked Randomization".

Blinding (investigator's opinion)

Single blinded

Blinding description

Since this is a single-blind study, our blindness would be single-blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of kashan University of Medical Science

Street address

Ghotb-e-Ravandi Blvd, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Approval date

2017-10-12, 1396/07/20

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1396.47

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

Allergic rhinitis

ICD-10 code

J30.1

ICD-10 code description

Allergic rhinitis due to pollen

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

Interleukin 25

Timepoint

First and 24 weeks after intervention

Method of measurement

ELISA

2**Description**

Interleukin 33

Timepoint

First and 24 weeks after intervention

Method of measurement

ELISA

Secondary outcomes**1****Description**

Disease severity

Timepoint

At the beginning of the study and 24 weeks after the intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Sublingual immunotherapy with drops manufactured by Wolwopharm in China with doses up to maintenance levels two drops of 1000 micrograms sublingual and for 6 months

Category

Treatment - Drugs

2

Description

Control group: oral Cetirizine 10 mg daily plus nasal spray mometasone every 12 hours a puff in each nasal cavity

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital of Kashan

Full name of responsible person

Hassan Nikouejad

Street address

Ghotb-e-Ravandi Blvd, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 2999

Email

hnikuinejad@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

Ghotb-e-Ravandi Blvd, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 2999

Email

research@kaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hassan Nikouejad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Immunology

Street address

Ghotb-e-Ravandi Blvd

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 2999

Fax

Email

hnikuinejad@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hassan Nikouejad

Position

Associate professo

Latest degree

Specialist

Other areas of specialty/work

Immunology

Street address

Ghotb-e-Ravandi Blvd

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 2999

Fax**Email**

hnikuinejad@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Mohammadhossein Pourhanifeh

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

No.1, Hekmat 77th Alley, Ghotb-e-Ravandi Blvd,
Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5558 0988

Fax**Email**

mhph.lord.1996@gmail.com

Web page address**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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available