

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### 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.

#### Protocol summary

##### Study aim

The Purpose of this Study was to compare the Efficacy of Sublingual Immunotherapy with Routine Medical Treatment and It's 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, sever 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

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##### Province

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##### Postal code

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##### 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**

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**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

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Kashan

**City**

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**Province**

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8715988141

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+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