

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of Regulatory T cells in allergic rhinitis patients: before and after one year of immunotherapy

#### Protocol summary

2015-12-02, 1394/09/11

#### Summary

Objective: Subcutaneous immunotherapy with specific allergen in allergic rhinitis is the only effective approved procedure. Aim of this study is evaluation of inhibitory responses by subcutaneous immunotherapy in allergic rhinitis treatment. Design: Inhibitory responses of regulatory cells are considered by evaluation of cytokines lymphocytes changes before and after the treatment by subcutaneous immunotherapy. Setting and conduct: Lymphocyte changes for 23 patients with perennial allergic rhinitis are done before and after treatment of subcutaneous immunotherapy by real time PCR. Participants: 23 patients of perennial allergic rhinitis ranged between 10 to 45 years old, residence in Mashhad, have positive skin test to the local common aeroallergens and are willing to cooperate in the project, are entered to study. Also patients with seasonal allergic rhinitis, history of autoimmune disease and allergic asthma are excluded the study. Intervention: Subcutaneous injection of condensed allergens based on the approved protocol of American Academy of Asthma, Allergy and Immunology are performed for patients. Main outcome: Lymphocytes changes of cytokines including IFN gamma, IL 10, IL 4, FOXP3, GITR and TGF beta before and after the treatment of subcutaneous immunotherapy are evaluated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015071623235N1**

Registration date: **2015-12-02, 1394/09/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

#### 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

Vice chancellor for research, Mashhad University of Medical Sciences

#### Expected recruitment start date

2010-05-23, 1389/03/02

#### Expected recruitment end date

2011-06-23, 1390/04/02

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of Regulatory T cells in allergic rhinitis patients: before and after one year of immunotherapy

#### Public title

Immunological changes of Immunotherapy in allergic rhinitis

#### Purpose

Basic science

#### Inclusion/Exclusion criteria

Inclusion criteria: All patients with persistent allergic rhinitis aged 45-10 years; Residence in Mashhad that have positive skin test to the local common aeroallergens and are willing to cooperate in the project. Exclusion criteria: Patients with seasonal allergic rhinitis, patients who have a history of autoimmune disease; Patients who consumed steroids or immunosuppressive drugs and effective on immune system; Pregnant women; Patients with immune deficiencies diseases, Patients with allergic asthma; Patients with malnutrition

**Age**

From **10 years** old to **45 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **25**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**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**

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

**City**

Mashhad

**Postal code****Approval date**

2014-01-19, 1392/10/29

**Ethics committee reference number**

89019

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

Allergic Rhinitis

**ICD-10 code**

J30.3

**ICD-10 code description**

Perennial allergic rhinitis

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

Cytokines Variations

**Timepoint**

Comparison baseline and terminal sample, after one year of treatment course

**Method of measurement**

Measuring selective cytokines by Real time PCR

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

Systemic reactions to immunotherapy

**Timepoint**

Each immunotherapy session

**Method of measurement**

Clinical evaluation

**Intervention groups****1****Description**

Subcutaneous injection of condensed allergens based on the approved protocol of American Academy of Asthma, Allergy and Immunology

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Allergy Clinic of Ghaem Hospital

**Full name of responsible person**

Dr Mohammad Ali Zamani

**Street address**

Ghaem Hospital, Mashhad University of Medical Sciences

**City**

Mashhad

**2****Recruitment center****Name of recruitment center**

Allergy Clinic of Dr Reza Farid Hosseini

**Full name of responsible person**

Dr Reza Faridhosseini

**Street address**

Chamran 7, Jahanbani Street

**City**

Mashhad

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences, Vice  
chancellor for research

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Central Building of Mashhad University of Medical  
Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

**City**

Mashhad

**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, Vice chancellor  
for research

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Ali Zamani

**Position**

Fellowship of pediatric Allergy

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Allergy Research Center, School of Medicine,  
Mashhad University of Medical Sciences, Mashhad,  
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**Full name of responsible person**

Dr Reza Farid Hosseini

**Position**

Professor of Immunology, Associate Professor of  
Clinical Immunology and Allergy

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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Immunology Research Center

**Full name of responsible person**

Hadis Yousefzadeh

**Position**

PhD by Research student of Immunology

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**  
*empty*

**Data Dictionary**  
*empty*