Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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

2015-12-02, 1394/09/11

Registrant information

Name
Farahzad Jabbari Azad
Name of organization / entity
Allergy Research Center, Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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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 Immmunotherapy in allergic rhinitis

Purpose

Basic scienece

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

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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, Iran

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

Name of organization / entity

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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BuAli Research Institute, BuAli Square

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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