

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Rush Immunotherapy effects on the gene expression of IL- 4, FoxP3, TGF- β , IL-17, IL-10 and IFN- γ in the perennial allergic rhinitis patients

Protocol summary

Summary

The aim of this study was detection of the effects of Rush Immunotherapy on the gene expression of IL- 4, FoxP3, TGF- β , IL-17, IL-10 and IFN- γ in the perennial allergic rhinitis patients. The study involved 16 patients with perennial allergic rhinitis ranged in age from 15 to 51 years referred to Ghaem Hospital, allergy ward, Mashhad University of Medical Sciences, Mashhad, Iran. Sixteen patients received rush immunotherapy. Quality of life and clinical symptoms of all patients before and after 3 months immunotherapy were completed in questionnaires namely Mini RQLQ and SNOT22, respectively. Blood samples were collected before and after 3 months of immunotherapy. RNA extraction and cDNA synthetize were performed to evaluate the gene expression of FoxP3, TGF- β , IL-17, IL-10, IL-4 and IFN- γ by Real time RT-PCR. Inclusion criteria: the patients with perennial allergic rhinitis between the ages of 15-51 years who had a positive skin test with aero allergens were enrolled to the study. Exclusion criteria: the patients who had history of autoimmune disease, Consumption of immunosuppressive drugs for reasons other than allergic diseases, pregnant women, immunocompromised patients, patients who had uncontrolled allergic asthma and patients who suffered from malnutrition were excluded. Intervention: Injection of concentrated extracts of allergens (salt grass, combined weeds) for immunotherapy was performed by allergist. The main consequence of the study was the evaluation of the gene expression related to FoxP3, TGF- β , IL-17, IL-10, IL-4 and IFN- γ following the rush immunotherapy in patients with allergic rhinitis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050723235N10**

Registration date: **2017-11-04, 1396/08/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-04, 1396/08/13

Registrant information

Name

Farahzad Jabbari Azad

Name of organization / entity

Allergy Research Center, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 51 1801 2770

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Rush Immunotherapy effects on the gene expression of IL- 4, FoxP3, TGF- β , IL-17, IL-10 and IFN- γ in the perennial allergic rhinitis patients

Public title

The impact of rapid desensitization in gene expression mediated by the immune system

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The risk of perennial allergic rhinitis; Positive skin test to allergens in the air; Clinical signs associated with skin test
Exclusion criteria: History of autoimmune disease; Patients with systemic corticosteroids or immunosuppressive drugs for reasons other than allergic disease on the immune system use to be effective; Pregnancy; Immunocompromised patients, patients who have uncontrolled allergic asthma; Patients with malnutrition; Patients who received beta-blocker drugs; Patients with a history of anaphylaxis; patients With coexisting cardiovascular disease; During treatment, patients who are experiencing systemic reactions; Patients with mental disorders

Age

From **15 years** old to **51 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **16**

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

Ghoreishi building Ethics Committee of Mashhad University of Medical Science

City

Mashhad

Postal code**Approval date**

2016-11-12, 1395/08/22

Ethics committee reference number

IR.MUMS.REC.1395.398

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

Perennial allergic rhinitis

ICD-10 code

J30.3

ICD-10 code description

Other allergic rhinitis

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

Changes in the expression of IL- 4, FoxP3, TGF- β , IL-17, IL-10 and IFN- γ genes in peripheral blood of allergic rhinitis patients

Timepoint

Before & 3 months after the trial

Method of measurement

Real Time-PCR Technique

2**Description**

Quality of life

Timepoint

Before and 3 months after Rush immunotherapy

Method of measurement

Questionnaires SNOT22 and Mini RQLQ

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

Systemic reactions to immunotherapy

Timepoint

At every turn immunotherapy

Method of measurement

Clinical

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

Subcutaneous immunotherapy with the Aero allergens

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center

Allergy Clinic Ghaem Hospital

Full name of responsible person

Amirabass Salmani

Street address

Ghaem Hospital, Ahmad Abad Street, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Ghoreishi, Daneshgah Ave, Mashhad

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Mashhad University of Medical Sciences

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

Amirabass Salmani

Position

Msc

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

Farahzad Jabbari Azad

Position

Associate Professor

Other areas of specialty/work

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Full name of responsible person

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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

