Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 commitie of Mashahd University of Medical Sciences
Street address
Ghoreishi building Ethics Committee of Mashahd 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
Befor & 3 months after the trial
Method of measurement
Real Time-PCR Technique

2

Description
Quality of life
Timepoint
Befor 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

Mashahd University of Medical Sciences

Full name of responsible person

Amirabass Salmani

Position

Msc

Other areas of specialty/work

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Name of organization / entity

Allergy Research Center, School of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran

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Associate Professor

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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*