

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Evaluation of clinical and immunological efficacy of sub lingual immunotherapy in patients with allergic rhinitis sensitive to mite

Protocol summary

Summary

The aim of this study was to determine the effect of sublingual immunotherapy on clinical symptoms and gene expression level of Foxp3 regulatory T cells, IL-10 and Transforming Growth Factor Beta and IL -17 compared with placebo in allergic rhinitis sensitive to mites. The main inclusion criteria, suffering from perennial allergic rhinitis and being sensitive to mites and the main exclusion criteria are having history of autoimmune disease, consumption of corticosteroids or immunosuppressive drugs and allergic asthma. . After obtaining parental consent, randomly divided into two groups treated with a condensed drops of mites or placebo. Before starting treatment, at regular intervals and after 6 months of treatment, based on standard questionnaires and clinical examination, the severity and extent of anti-allergy drugs were recorded. At the beginning and end of the project in 10 ml heparin blood brachial vein taken from the patient's immunological tests to check the levels of gene expression changes in regulatory T cells.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042323235N9**

Registration date: **2017-05-10, 1396/02/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-10, 1396/02/20

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

Mashhad University of Medical Sciences

Expected recruitment start date

2010-03-20, 1388/12/29

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of clinical and immunological efficacy of sub lingual immunotherapy in patients with allergic rhinitis sensitive to mite

Public title

Sub lingual immunotherapy of Nasal allergies

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: approved clinical perennial allergic rhinitis and laboratory diagnosis; the desire of patients to drug treatment and participation in the project Exclusion criteria: Suffering from seasonal allergic rhinitis, a history of autoimmune disease, Consumption of corticosteroids or immunosuppressive drugs, pregnancy, allergic

asthma, malnutrition

Age
From **5 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashahd University of Medical Sciences

Street address

Ghoreishi building Ethics Committee of Mashahd University of Medical Science

City

Mashhad

Postal code

Approval date

2010-10-27, 1389/08/05

Ethics committee reference number

IR.MUMS.REC.1389.82

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

Clinical symptoms of allergic rhinitis

Timepoint

After six month

Method of measurement

questionnaire

Secondary outcomes

1

Description

FOXP3 gene expression

Timepoint

After six month

Method of measurement

Real-Time PCR

2

Description

Interlukin-10

Timepoint

After six month

Method of measurement

Real-Time PCR

3

Description

Tumor Groeth Factor-B

Timepoint

After six month

Method of measurement

Real-Time PCR

4

Description

Interlukin-17

Timepoint

After six month

Method of measurement

Real-Time PCR

Intervention groups

1

Description

In Intervention group received Extract drops of mite via sublingual administration for 6 months

Category

Treatment - Drugs

2

Description

In control group received placebo via for 6 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Allergy Clinic Ghaem Hospital

Full name of responsible person

Dr Farahzad Jabbari Azad

Street address

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

Mashad University of Medical Sciences

Full name of responsible person

Homa sadri

Position

Medical student

Other areas of specialty/work

Street address

Allergy Research Center, Ghaem Hospital, Ahmadabad Street, Mashhad

City

Mashhad

Postal code

Phone

+98 518012770

Fax

Email

homasadri7@gmail.com

Web page address

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, MD

Position

Associate Professor

Other areas of specialty/work

Street address

Allergy Research Center, Ghaem Hospital, Ahmadabad Ave, Mashhad

City

Mashhad

Postal code

Phone

+98 518012770

Fax

Email

jabbarif@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Homa Sadri

Position

Other areas of specialty/work

Street address

City

Mashhad

Postal code

Phone

Fax

Email

homasadri7@gmail.com

Web page address

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