

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of the Effectiveness of Intralymphatic Allergen Immunotherapy in patients with Allergic Rhinitis

Protocol summary

Allergic Rhinitis Symptom; Quality Of Life; Adverse Reaction; Salsola Specific IgE

Study aim

Treatment of Allergic Rhinitis

Design

Clinical Trial Without Control Group And Comparisons Of Individuals With Each Other

Settings and conduct

patients with pollen-induced rhinoconjunctivitis were treated with 3 intralymphatic inguinal injections of Greer 1000 SQ-U Salsola Kali Allergen Extract With 4 Weeks Interval . Clinical effects (SNOT22 Questionnaire), safety and circulating Salsola Kali Specific IgE were assessed before, 4 weeks after treatment and at the End Of The Consecutive Pollen Season And Comparisons Of Individuals With Each Other.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Patients With Seasonal Or Perennial Allergic Rhinitis That Have Aggravated Symptoms From Mid Summer till Mid Autumn For At Least Two Years... 2) Age :15-68 Years 3)Positive Skin Prick Test Response, Defined As Wheal Diameter ≥ 3 mm , To Salsola Kali 4)A Clinical History Of Rhinoconjunctivitis That Remains Troublesome Despite Treatment With Either Antihistamines Or Nasal Corticosteroids During The Weed Pollen Season 5) The Ability To Give Informed Consent And Comply With Study Procedures Exclusion criteria 1. Previous Allergen Immunotherapy 2. History Of Asthma 3. At Screening Visit, Current Symptoms Of, Or Treatment For, Upper Respiratory Tract Infection 4. History Of Life-Threatening Anaphylaxis Or Angioedema 5. Ongoing Systemic Immunosuppressive Treatment 6. The Presence Of Any Medical Condition Such As Malignancy, Autoimmune Disease ,Immunodeficiency Or Any Other Chronic Disease 7.History Of Drug Consumption Such As ACE_Inhibitor, Beta Blocker, MAO Inhibitor 8. Pregnancy

Intervention groups

18 to 65 Year Old Patients With Persistent Allergic Rhinitis

Main outcome variables

General information

Reason for update

Acronym

ILIT

IRCT registration information

IRCT registration number: **IRCT20161206031256N2**

Registration date: **2018-03-02, 1396/12/11**

Registration timing: **retrospective**

Last update: **2018-03-02, 1396/12/11**

Update count: **0**

Registration date

2018-03-02, 1396/12/11

Registrant information

Name

Maryam Khoshkhui

Name of organization / entity

Mashhad university

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2770

Email address

khoshkhui@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice President of Research of Mashhad University of Medical Sciences

Expected recruitment start date

2017-04-03, 1396/01/14

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

2017-04-03, 1396/01/14

Actual recruitment end date

2017-06-20, 1396/03/30

Trial completion date

empty

Scientific title

Evaluation of the Effectiveness of Intralymphatic Allergen Immunotherapy in patients with Allergic Rhinitis

Public title

Effects of Intralymphatic Allergen Immunotherapy in treatment of allergic rhinitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with Seasonal or Perennial Allergic Rhinitis Aggravated symptoms from mid Summer till mid Autumn for at least two years Age :15-65 years Positive Skin Prick Test response to Salsola Kali Symptoms remain troublesome despite treatment The ability to comply with study procedures

Exclusion criteria:

Past history of Autoimmune Diseases Ongoing Systemic Immunosuppressive treatment. The presence of Pregnancy The presence of Immunodeficiency The presence of Allergic Asthma The presence of Heart Diseases Ongoing Beta Blocker or ACE inhibitors drug usage The presence of Malignancy The presence of any chronic diseases Current symptoms of Upper Respiratory Tract Infection History of life-threatening Anaphylaxis or Angioedema

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **15**

Actual sample size reached: **15**

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**

Mashahd University of Medical Sciences

Street address

Ghoreishi building Ethics Committee of Mashahd University of Medical Science

City

Mashhad

Province

Razavi Khorasan

Postal code

9175711111

Approval date

2017-03-21, 1396/01/01

Ethics committee reference number

IR.MUMS.fm.REC.1395.547

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

Allergic Rhinitis

ICD-10 code

J30.1

ICD-10 code description

Allergic rhinitis due to pollen

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

Clinical Symptoms, Drug Usage, Skin Prick Test, Specific IgE

Timepoint

Before The Trial

Method of measurement

Sign And Symptoms, Antiasthmatic Drugs Usage, Skin Prick Test, Peakflowmetry and Specific IgE

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

Clinical symptoms, drug usage, specific IgE

Timepoint

One month after end of treatment

Method of measurement

Physical examination and peakflowmetry

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

3 intralymphatic inguinal injections under the guide of sonography(1000 SQ-U Salsola-pollen extract within 4 weeks interval).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital, Allergy Clinic

Full name of responsible person

Nasrin Sadat Motevalli Haghi

Street address

Ghaem Hospital, Shariati Ave

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dr.haghi@yahoo.com

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 building, Daneshgah Ave, Mashhad

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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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad Unevesity of Medical Science

Full name of responsible person

Nasrin Sadat Motevalli Haghi

Position

fellow in training immunology and allergy

Latest degree

Specialist

Other areas of specialty/work

Immunology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences, Allergy Research center

Full name of responsible person

Maryam Khoshkhui

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

intralymphatic allergen immunotherapy

When the data will become available and for how long

6 month after study

To whom data/document is available

every one

Under which criteria data/document could be used

choosing new management

From where data/document is obtainable

internet searching

What processes are involved for a request to access data/document

google

Comments