Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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

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
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Iran (Islamic Republic of)
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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
Befor 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

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Maryam Khoshkhui

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Immunology

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Person responsible for updating data

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Latest degree

Specialist

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