

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The evaluation of the clinical response to subcutaneous immunotherapy in patients with allergic rhinitis

Protocol summary

Study aim

This study is aimed to evaluate the clinical response of subcutaneous immunotherapy in patients with allergic rhinitis

Design

This study will be a single arm clinical trial and recruit 50 individuals in 2 years. With respect to the nature of the study no randomization will be performed.

Settings and conduct

This clinical study will be performed at Imam Ali clinic of Shahrekord city. Patients with diagnosis of allergic rhinitis will be recruited based on the inclusion and exclusion criteria. thereafter, they will be followed for two years from the start of treatment. With respect to the nature of the study no blinding will be performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of allergic rhinitis, positive prick test (in this study induration and erythema of more than 3mm after prick test is considered positive prick test), negative pregnancy test and written informed consent to participate in the study. Exclusion criteria: concomitant microbial rhinosinusitis, Autoimmune diseases, malignancies, and usage of beta blockers.

Intervention groups

The extract of respiratory allergens of Chaharmahal and Bakhtiyari province will be prepared by Dome Hollister company in United States of America. Immunotherapy schedule for injection of the extract with vial dilution of 1:10000pg is one injection every week for ten weeks and one injection with dilution of 1:1000pg every other week for the other ten weeks and one injection monthly from dilution of 1:100pg for one year. Therapeutic doses starts from 0.05ml of 1:10000 vials and increases to maximum amount of 0.5ml of 1:100 in the end of immunotherapy session.

Main outcome variables

Prevalence of allergic rhinitis symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170201032346N6**

Registration date: **2020-12-30, 1399/10/10**

Registration timing: **retrospective**

Last update: **2020-12-30, 1399/10/10**

Update count: **0**

Registration date

2020-12-30, 1399/10/10

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 91155226108

Email address

firoozihosein@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

2014-04-21, 1393/02/01

Actual recruitment end date

2016-04-20, 1395/02/01

Trial completion date

2019-04-21, 1398/02/01

Scientific title

The evaluation of the clinical response to subcutaneous

immunotherapy in patients with allergic rhinitis

Public title

The evaluation of the clinical response to immunotherapy in patients with allergic rhinitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Positive Prick test (induration and erythema for more than 3mm is considered positive prick test) Allergic Rhinitis Negative pregnancy test Informed consent 5 to 65 years of age

Exclusion criteria:

Absence of concomitant viral, fungal or bacterial rhinosinusitis Autoimmune disease Malignancy Use of beta-blockers

Age

From **5 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **50**

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 Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Vice Chancellor of Research, Moalem st, Moalem sq, Sari, Mazandaran, Iran.

City

Sari

Province

Mazandaran

Postal code

4816715793

Approval date

2016-05-10, 1395/02/21

Ethics committee reference number

IR.MAZUMS.REC.1395.2784

Health conditions studied

1

Description of health condition studied

Allergic rhinitis

ICD-10 code

J30.9

ICD-10 code description

Allergic rhinitis, unspecified

Primary outcomes

1

Description

Sneezing

Timepoint

Before intervention, 2 years after intervention

Method of measurement

Checklist containing clinical symptoms

2

Description

Postnasal dripping

Timepoint

Before intervention, 2 years after intervention

Method of measurement

Checklist containing clinical symptoms

3

Description

Nasal congestion

Timepoint

Before intervention, 2 years after intervention

Method of measurement

Checklist containing clinical symptoms

4

Description

Itchy throat

Timepoint

Before intervention, 2 years after intervention

Method of measurement

Checklist containing clinical symptoms

5

Description

Itchy eyes

Timepoint

Before intervention, 2 years after intervention

Method of measurement

Checklist containing clinical symptoms

6

Description

Rhinorrhea

Timepoint

Before intervention, 2 years after intervention

Method of measurement

Checklist containing clinical symptoms

7

Description

Cough

Timepoint

Before intervention, 2 years after intervention

Method of measurement

Checklist containing clinical symptoms

8

Description

Sleep disturbance

Timepoint

Before intervention, 2 years after intervention

Method of measurement

Checklist containing clinical symptoms

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who has a positive prick test will undergo immunotherapy with allergen extract with three vials diluted 1:10000 pg per week for 10 sessions, 1:1000 pg every other week for 10 sessions and then dilution of 1: 100 pg every month for 1 year.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Clinic

Full name of responsible person

Mohammad Ali Zamani

Street address

Shariati Blvd.

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816788640

Phone

+98 38 3224 2696

Email

Zamani.m@skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ramsar Campus, Mazandaran University of Medical Sciences

Full name of responsible person

Davood Farzin

Street address

No.20 ,Taleghani Ave., Ramsar.

City

Ramsar

Province

Mazandaran

Postal code

4691786953

Phone

+98 11 5522 6108

Email

firoozihosein@mazums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ramsar Campus, Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Firouzi Hossein

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

No.20 ,Taleghani Ave., Ramsar.

City

Ramsar

Province
Mazandaran
Postal code
4691786953
Phone
+1 155230181
Fax
Email
firoozihosein@mazums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Firouzi Hossein
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
No.20 ,Taleghani Ave., Ramsar.
City
Ramsar
Province
Mazandaran
Postal code
4691786953
Phone
+1 155230181
Fax
Email
firoozihosein@mazums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Firouzi Hossein
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work

Pediatrics
Street address
No.20 ,Taleghani Ave., Ramsar.
City
Ramsar
Province
Mazandaran
Postal code
4691786953
Phone
+1 155230181
Fax
Email
firoozihosein@mazums.ac.ir
Web page address

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected deidentified data for primary and secondary outcome measures are going to be shared

When the data will become available and for how long

After publishing the study, data are going to be available

To whom data/document is available

Data are going to be available to all researchers and clinician irrespective to their employment sector

Under which criteria data/document could be used

Permission are granted upon request for secondary and meta-analysis

From where data/document is obtainable

Requests are gathered through principle researcher's e-mail address

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

Upon verification of request and reason data are given in three month.

Comments