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
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Other areas of specialty/work
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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