

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of immunotherapy with aeroallergens and drug treatment in patients with allergic rhinitis

Protocol summary

Study aim

Comparison of the therapeutic response of immunotherapy with aeroallergens and drug treatment in patients with allergic rhinitis referred to Imam Ali Clinic

Design

Double-blind randomized clinical trial with parallel and 2 intervention groups, with a sample size of 120

Settings and conduct

This study was performed on 120 patients with allergic rhinitis who referred to Imam Ali clinic in Shahrekord. Patients will be randomly assigned to one of the two intervention groups by selecting a code. Patients and researcher are unaware of the type of treatment that each group receives. A group received common drug treatment included inhaled glucocorticoids and antihistamines once a day for one month, and the other group after doing the prick test and if it was positive underwent immunotherapy with aeroallergens prepared by American Hollister animal husbandry company. Then, the response to treatment was measured based on the patient's satisfaction with symptom improvement.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 10 and over 10 years; Age less than 50 years; Lack of advanced and severe asthma; Negative pregnancy test for women; Lack of autoimmune disease; Lack of immunodeficiency disease; Lack of malignancy; Exclusion criteria: Patient lack of cooperation; Continuous use of immunosuppressive drugs; Continuous use of antihistamines; Taking beta-blocker medications; History of allergy to each of the treatment groups

Intervention groups

Intervention groups include the group receiving the usual drug treatment, including inhaled glucocorticoids (fluticasone) and antihistamines, and the group under immunotherapy with allergens.

Main outcome variables

Clinical response, Patients' satisfaction with symptom therapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N15**

Registration date: **2019-07-11, 1398/04/20**

Registration timing: **prospective**

Last update: **2019-07-11, 1398/04/20**

Update count: **0**

Registration date

2019-07-11, 1398/04/20

Registrant information

Name

Sadra AnsariPour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 31 3650 3487

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st_ansari.s@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of immunotherapy with aeroallergens and drug treatment in patients with allergic rhinitis

Public title

Comparison of immunotherapy with aeroallergens and drug treatment in patients with allergic rhinitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 10 and over 10 years Age less than 50 years Lack of advanced and severe asthma Negative pregnancy test for women Lack of autoimmune disease Lack of immunodeficiency disease Lack of malignancy

Exclusion criteria:

Patient lack of cooperation Continuous use of immunosuppressive drugs Continuous use of antihistamines Taking beta-blocker medications History of allergy to each of the treatment groups

Age

From **10 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize the study, simple randomization with individual unit was used, so that patients randomly selected one of the cards containing the code A or B so they entered one of the two treatment groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Vice chancellor for research, Building No. 2,
University headquarters, Ayatollah Kashani Blvd

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713492

Approval date

2018-07-22, 1397/04/31

Ethics committee reference number

IR.SKUMS.REC.1397.117

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

Sneeze

Timepoint

Before intervention, 2 years after intervention

Method of measurement

Checklist containing clinical symptoms

2

Description

Cough

Timepoint

Before intervention, 2 years after intervention

Method of measurement

Checklist containing clinical symptoms

3

Description

Rhinorrhea

Timepoint

Before intervention, 2 years after intervention

Method of measurement

Checklist containing clinical symptoms

4

Description

Itchy eyes

Timepoint

Before intervention, 2 years after intervention

Method of measurement

Checklist containing clinical symptoms

5

Description

Itchy throat
Timepoint
Before intervention, 2 years after intervention
Method of measurement
Checklist containing clinical symptoms

6

Description
Post nasal discharge
Timepoint
Before intervention, 2 years after intervention
Method of measurement
Checklist containing clinical symptoms

7

Description
Nasal congestion
Timepoint
Before intervention, 2 years after intervention
Method of measurement
Checklist containing clinical symptoms

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients received the usual drug treatment, including inhaled glucocorticoids (Fluticasone) and antihistamines once a day for one month.
Category
Treatment - Drugs

2

Description
Intervention group: Patients who had a positive prick test underwent immunotherapy with allergen extract with three vials diluted 1: 10,000 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 2 years.
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., Imam Ali Clinic
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Shahrekord

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Chahar-Mahal-va-Bakhtiari
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8816788640
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Zamani.m@skums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr. seyed Kamal Solati(Associate Professor of Psychology)
Street address
Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd
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kamal_solati@yahoo.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Mohammad Ali Zamani
Position
Assistant Professor
Latest degree
Specialist

Other areas of specialty/work

Immunology

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Shahrekord University of Medical Sciences, Building
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Information on the main outcome can be shared.

When the data will become available and for how long

Start the access period 4 months after publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Use data to complete clinical trial studies

From where data/document is obtainable

Kashani Hospital in Shahrekord, zamani.m@skums.ac.ir

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

After the investigation of researcher request and presentation of required documents will be accessible.

Comments