

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 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 Ansari pour

##### Name of organization / entity

Shahrekord University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3650 3487

##### Email address

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

**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**

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

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8815713471

**Phone**

+98 38 3334 2414

**Email**

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

**Street address**

Shahrekord University of Medical Sciences, Building  
No. 2, University headquarters, Ayatollah Kashani  
Blvd

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8815713471

**Phone**

+98 38 3334 2414

**Email**

zamani.m@skums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Zamani

**Position**

Assistant Professor

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Specialist

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Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8815713471

**Phone**

+98 38 3227 4004

**Email**

zamani.m@skums.ac.ir

**Person responsible for updating data****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**

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**Postal code**

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**Phone**

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**Email**

zamani.m@skums.ac.ir

**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 resercher request and  
presentation of required documents will be accessible.

**Comments**