# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Evaluation of Omalizumab Therapeutic Effects in Mild to Moderate Psoriatic Patients Resistant to Routine Topical Treatments

## Protocol summary

**Study aim**
Evaluation of Omalizumab Therapeutic Effects in Mild to Moderate Psoriatic Patients Resistant to Routine Topical Treatments

**Design**
Randomized clinical trial

**Settings and conduct**
1. Dermatology Clinic, Imam Reza Hospital, Mashhad 2. Allergy Clinic, Qaem Hospital, Mashhad

**Participants/Inclusion and exclusion criteria**
Inclusion: A) Patients with mild to moderate psoriasis (with PASI more than 10-15 and less than 30-40) with more than 10-15% involvement and whose disease is not so mild and limited to respond to routine topical treatment (they have received routine topical treatment and have not reached the minimum acceptable therapeutic response*), And it was not so severe and extensive that needs severe stage treatments (with too many side effects). * Minimum acceptable therapeutic response: BSA less than 3% or BSA reduction greater than 75% (compared to the time of starting treatment) at 3 months after starting treatment. B) Patients living in remote areas who cannot travel a long distance receive phototherapy 3 times a week and for a long period of time. C) 30-50 years old Exclusion: Refusal to continue participation in the study Past anaphylaxis history

**Intervention groups**
1. Main Treatment Group: monthly subcutaneous injection of two vials of Omalizumab 150 mg/5ml for six months. 2. Placebo Group: monthly injection of two vials of distilled water 5 ml for six months. (A dermatologist will visit patients monthly in the first two months, and every two months in the next four months of the study. The clinical course of the disease will be evaluated in these visits.)

**Main outcome variables**
Psoriasis Area and Severity Index,PASI

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20150716023235N18**
Registration date: **2023-09-26, 1402/07/04**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-26, 1402/07/04**
Update count: **0**

**Registration date**
2023-09-26, 1402/07/04

**Registrant information**

**Name**
Farahzad Jabbari Azad

**Name of organization / entity**
Allergy Research Center, Mashhad University of Medical Sciences

**Country**
Iran (Islamic Republic of)

**Phone**
+98 51 1801 2770

**Email address**
jabbarif@mums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-09-23, 1402/07/01

**Expected recruitment end date**
2024-09-22, 1403/07/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Evaluation of Omalizumab Therapeutic Effects in Mild to Moderate Psoriatic Patients Resistant to Routine Topical Treatments

**Public title**
Treatment with Omalizumab in Psoriatic Patients

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Patients with mild to moderate psoriasis (with PASI more than 10-15 and less than 30-40) with more than 10-15% involvement and whose disease is not so mild and limited to respond to routine topical treatment (they have received routine topical treatment and have not reached the minimum acceptable therapeutic response*), And it was not so severe and extensive that needs severe stage treatments (with too many side effects). *Minimum acceptable therapeutic response: BSA less than 3% or BSA reduction greater than 75% (compared to the time of starting treatment) at 3 months after starting treatment. Patients living in remote area who cannot travel a long distance to receive phototherapy 3 times a week and for a long period of time. 30-50 years old

**Exclusion criteria:**
Prior history of Omalizumab injection Prior history of receiving systemic treatments for psoriasis such as Methotrexate, Ciclosporin, Acitretin, Etanercept, Adalimumab, Infliximab, and Ustekinumab. Prior history of phototherapy Past anaphylaxis history

**Age**
From **30 years** old to **50 years** old

**Gender**
Both

**Phase**
2

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**
Target sample size: **20**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
The participants are divided into two groups by a simple randomization method using a table of random numbers tool. The randomization unit is individual. The random sequence is such that people who received an odd number enter the intervention group, and people with an even number are placed in the control group. Patients and outcome assessors will be unaware of the assigned numbers, and concealment will be performed.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
Patients and outcome assessors (dermatologist and clinical allergist and immunologist) will be unaware of the assigned groups and double blinding will be performed. But the ward nurses who are responsible for injecting the intervention or placebo, as well as the data analyst, will not be blinded. Even numbers (for the control group) and odd numbers (for the intervention group) are written in separate envelopes or written in the sheets and the sheet is folded so that it cannot be seen inside. Upon entry of each eligible patient, an envelope/sheet is removed and the patient is treated according to the number (group) inside.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee in Biomedical Research of Imam Reza Hospital, Vice Presidency of Mashhad University

**Street address**
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

**City**
Mashhad

**Province**
Razavi Khorasan

**Postal code**
91778-99191

**Approval date**
2023-08-14, 1402/05/23

**Ethics committee reference number**
IR.MUMS.IRH.REC.1402.114

## Health conditions studied

### 1

**Description of health condition studied**
Psoriasis

**ICD-10 code**
L40.9

**ICD-10 code description**
Psoriasis, unspecified

## Primary outcomes

### 1

**Description**
Psoriasis Severity

**Timepoint**
At 5 timepoints, before, during and after intervention (month O, 1, 2, 4, and 6)

**Method of measurement**
Psoriasis Area and Severity Index (PASI)

## Secondary outcomes

### 1

**Description**
Dermatology Life Quality
**Timepoint**
Before intervention and after 6 months of intervention
**Method of measurement**
Dermatology Life Quality Index; DLQI

### 2

**Description**
Serum Total IgE Level
**Timepoint**
Before intervention and after 6 months of intervention
**Method of measurement**
Elisa

## Intervention groups

### 1

**Description**
The main intervention group: for this group, 2 vials of omalizumab 150 mg per month (total of 300 mg per month) will be injected subcutaneously for 6 times with monthly intervals. The injection of this medicine will be done in the allergy department by the ward nurse under the supervision of the allergy and clinical immunology specialist. The volume of omalizumab vials will be 5 cc, for each injection, two vials will be drawn to a total volume of 10 cc inside a 10 cc syringe and will be injected subcutaneously. Patients will be monitored for signs of allergic reaction for 2 hours after injection, and then they will be discharged from the allergy department.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: For this group, 2 vials of 5 cc distilled water will be injected intravenously 6 times at monthly intervals. Distilled water injection will be done in the allergy department by the ward nurse under the supervision of the allergy and clinical immunology specialist. The volume of the vials of distilled water will be 5 cc; for each injection, two vials totaling 10 cc will be drawn into a 10 cc syringe and injected intravenously. Patients will be monitored for signs of allergic reaction for 2 hours after injection, and then they will be discharged from the allergy department.
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Allergy Clinic Ghaem Hospital
**Full name of responsible person**
Dr Farahzad Jabbari Azad
**Street address**
Ahmadabad street, at the Parastar corner
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9919-91766
**Phone**
+98 915 316 7868
**Email**
jabbarif@mums.ac.ir

### 2

**Recruitment center**
**Name of recruitment center**
Dermatology clinic of Imam Reza hospital
**Full name of responsible person**
Shatila Torabi
**Street address**
Dermatology clinic of Imam Reza hospital, Daneshgah Avenue
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9137913316
**Phone**
+98 915 513 1784
**Email**
TorabiSh@mums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Dr Mohsen Tafaghodi Piyadegheybi
**Street address**
Central Building of Mashhad University of Medical Sciences (Ghoreishi), Daneshgah 16, Daneshgah street
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
91778-99191

**Phone**
+98 51 3841 2081
**Email**
ramresearch@mums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
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 University of Medical Sciences
**Full name of responsible person**
Mehraneh Movahedi Aliabadi
**Position**
Research assistant of the Allergy Research Center of Mashhad
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Others
**Street address**
Department of Immunology and Allergy, Hospital Ghaem, Ahmadabad streets, Mashhad Mashhad
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9919-91766
**Phone**
+98 51 3801 2298
**Fax**
**Email**
movahhedam3@mums.ac.ir
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Farahzad Jabbari Azad, MD
**Position**
Professor, Director of the Allergy Research Center of Mashhad
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Allergy and Clinical Immunology
**Street address**
Department of Immunology and Allergy, Hospital Ghaem, Ahmadabad streets, Mashhad Mashhad
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9119-91766
**Phone**
+98 51 3845 8769
**Fax**
**Email**
Jabbarif@mums.ac.ir
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Mehraneh Movahedi Aliabadi
**Position**
Research assistant of the Allergy Research Center of Mashhad
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Others
**Street address**
Department of Immunology and Allergy, Hospital Ghaem, Ahmadabad streets, Mashhad
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9919-91766
**Phone**
+98 51 3801 2298
**Fax**
**Email**
movahhedam3@mums.ac.ir
**Web page address**

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

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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

**Title and more details about the data/document**

Not applicable

**When the data will become available and for how long**

Not applicable

**To whom data/document is available**

Not applicable

**Under which criteria data/document could be used**

Not applicable

**From where data/document is obtainable**

Not applicable

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

Not applicable

**Comments**