

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Therapeutic Effects of Adalimumab in Patients with Resistant Psoriasis Patients by DLQ and PASI Questionnaires

#### Protocol summary

##### Study aim

The aim of this study was to evaluate the effect of adalimumab in patients with refractory psoriasis

##### Design

Randomized clinical trial with control group, with parallel groups, without blinding, , phase 3 on 60 patients. Even and odd numbers were used for randomization.

##### Settings and conduct

This study was performed in Sina Hospital, Tabriz, dermatology ward, and there is no blinding. Patients in the intervention and control groups will be randomly evaluated using even and odd numbers.

##### Participants/Inclusion and exclusion criteria

Patients with confirmed psoriasis, non-response to previous treatments, no use of herbal medicines, and resistance to at least one systemic drug are included in the study. Patients with hypersensitivity to adalimumab and other underlying organ disorders are excluded from the study.

##### Intervention groups

Intervention group: At the beginning of the study, they will receive 80 mg of adalimumab. The next dose will be one week later (40 mg) and then every two weeks (40 mg) (the total duration of treatment will be two months). Control group: will receive routine psoriasis treatment including methotrexate and cyclosporine at a specific dose determined by a dermatologist (project manager).

##### Main outcome variables

Disease severity, Quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120524009844N8**

Registration date: **2020-10-20, 1399/07/29**

Registration timing: **retrospective**

Last update: **2020-10-20, 1399/07/29**

Update count: **0**

##### Registration date

2020-10-20, 1399/07/29

##### Registrant information

###### Name

Mehdi Amirnia

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1540 6612

###### Email address

amirniyam@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-21, 1399/04/01

##### Expected recruitment end date

2020-09-20, 1399/06/30

##### Actual recruitment start date

2020-07-22, 1399/05/01

##### Actual recruitment end date

2020-08-22, 1399/06/01

##### Trial completion date

2020-11-20, 1399/08/30

##### Scientific title

Therapeutic Effects of Adalimumab in Patients with Resistant Psoriasis Patients by DLQ and PASI Questionnaires

##### Public title

Therapeutic Effects of Adalimumab in Patients with Resistant Psoriasis

##### Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Confirmed psoriasis Accepted Patients without response to previous treatments Don't use of other drugs and herbal supplements Resistance to atleast one systemic treatment

### Exclusion criteria:

Allergy to Adalimumab Having active inflammation such as tuberculosis, malignancies and etc Neurological disorders Hematological disorders Moderate to severe heart failure Pregnant and breast feeding woman Mental retarded patients

### Age

From **18 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

Actual sample size reached: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomization will be done using even and odd numbers. The intervention group will be odd numbers and the control group will be even numbers. The number zero will be considered as an even.

### 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 Tabriz University of Medical Sciences

##### Street address

Third floor, Central Building 2 , Tabriz Medical Sciences University, Gholgasht ave , Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5163639888

#### Approval date

2020-08-10, 1399/05/20

## Ethics committee reference number

IR.TBZMED.REC.1399.537

## Health conditions studied

### 1

#### Description of health condition studied

Psoriasis

#### ICD-10 code

L40

#### ICD-10 code description

Psoriasis

## Primary outcomes

### 1

#### Description

Disease severity

#### Timepoint

At the beginning of the study, 1, 2, 3 and 4 months after receiving the intervention

#### Method of measurement

Psoriasis Area Severity Index Score

### 2

#### Description

Quality of life

#### Timepoint

Initiation of the study, 4 months after receiving the intervention

#### Method of measurement

Dermatologic Quality of Life Index

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: At the beginning of the study, they will receive 80 mg of adalimumab. The next dose will be one week later (40 mg) and then every two weeks (40 mg) (the total duration of treatment will be two months).

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Will receive routine psoriasis treatment including methotrexate and cyclosporine at a specific dose determined by a dermatologist (project manager).

#### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Sina Hospital

**Full name of responsible person**

Dr. Mehdi Amirnia

**Street address**

Azadi Street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

516369888

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**Email**

mehamir46@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Samiei

**Street address**

Vice chancellor for research, Tabriz University of Medical Sciences, Central Building of Medical Sciences, Daneshgah Square.

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**Email**

samieim@tbzmed.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mehdi Amirnia

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Faculty of medicine, Tabriz University of Medical Sciences, Golgasht st.

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mehdi Amirnia

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Associate Professor

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**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**

No - There is not 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**

Study data is categorized and coded with no identifiable individuals.

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

Access to study data after publication of the result is available in the journal.

**To whom data/document is available**

Anyone interested in using the data can access the study data.

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

Study data can be used for comparison with other results.

**From where data/document is obtainable**

Refer to the study's scientific or public accountability person for data.

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

The request will be sent by email to person responsible for scientific or public inquiries.

**Comments**