

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

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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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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

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Person responsible for scientific inquiries

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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