

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the efficacy of Adalimumab and Methotrexate in cases of moderate to severe psoriasis, a double-blind clinical trial

Protocol summary

Study aim

Comparison of the efficacy of Adalimumab and Methotrexate in cases of moderate to severe psoriasis.

Design

This is a parallel randomized controlled clinical trial that will be performed on 92 patients with moderate to severe psoriasis. Randomization in this research is done using quadri blocks using syntax written in SPSS program. In this study outcome evaluator and data analyzer are blinded.

Settings and conduct

This study will conduct as a clinical trial study with 92 patients who will refer to Imam Hossain Hospital of Shahroud. Patients must sign an informed consent form before entering the study. In this study outcome evaluator and data analyzer are blinded.

Participants/Inclusion and exclusion criteria

Including criteria: patients with moderate to severe psoriasis and having the satisfaction of participating in the project. Excluding criteria: history of severe burns or skin damage; existence of severe chronic hormonal disorders such as hypothyroidism; history of skin laser therapy in the past year; history of chronic liver and kidney disease and pregnancy or lactation.

Intervention groups

For patients in the intervention group, in addition to routine treatment, 80 mg of Adalimumab ampoule subcutaneously to begin and then 40 mg a week later as subcutaneously and then 40 mg subcutaneously every two weeks for 16 weeks. For patients in the control group, in addition to routine treatment (including topical 10% glycerin lotion and 25 mg hydroxyzine tablets three times daily), 20 mg of Methotrexate ampoule intramuscularly to start and then 10 mg intramuscularly one week later and then 10 mg intramuscularly will be administered every two weeks for 16 weeks.

Main outcome variables

Measurement of psoriasis severity index; Measure the percentage of surface area involved in the patient's body

and Measurement of redness of psoriasis rash.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100102002954N26**

Registration date: **2022-02-28, 1400/12/09**

Registration timing: **prospective**

Last update: **2022-02-28, 1400/12/09**

Update count: **0**

Registration date

2022-02-28, 1400/12/09

Registrant information

Name

Mohammad Bagher Sohrabi

Name of organization / entity

Shahroud University of Medical Sciences and Health

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-01, 1400/12/10

Expected recruitment end date

2022-07-06, 1401/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of Adalimumab and Methotrexate in cases of moderate to severe psoriasis, a double-blind clinical trial

Public title

Comparison of the effect of Adalimumab and Methotrexate in the treatment of psoriasis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range 55-15 years; Patients with a definite diagnosis of moderate to severe psoriasis; Having the satisfaction of participating in the project.

Exclusion criteria:

History of severe burns or skin damage; Existence of severe chronic hormonal disorders such as hypothyroidism; History of severe hirsutism; History of topical treatment of psoriasis with drugs and combined solutions in the last six months; History of skin laser in the past year; History of chronic liver and kidney disease; History of hormone therapy (estrogen or testosterone), Pregnancy or lactation,

Age

From **15 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were allocated to intervention and control groups according to random allocation table that illustrated by a statistician. Randomization was done using permuted block randomization method (Block size was 4) using blocked random allocation syntax in SPSS software. For calculation sample size was 92 and number of blocks was 23. Allocation concealment was done using closed opaque envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study outcome evaluator and data analyzer are blinded. The division of patients into two groups intervention and control, review and record treatment results is done by a qualified nurse who has no knowledge of the actions performed in the two groups. Data analysis will also be performed by a project epidemiologist who has no knowledge of patient grouping.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahrood University of Medical Sciences

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Shahrood University of Medical Sciences; 7 Tir squer, Shahrood

City

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Province

Semnan

Postal code

3616647555

Approval date

2022-01-05, 1400/10/15

Ethics committee reference number

IR.SHMU.REC.1400.239

Health conditions studied**1****Description of health condition studied**

Moderate to severe of psoriasis

ICD-10 code

L40.1

ICD-10 code description

Generalized pustular psoriasis

Primary outcomes**1****Description**

Measurement of psoriasis severity index

Timepoint

Beginning and end of the study

Method of measurement

Psoriasis Severity Index Calculator Software Version 1.7.2

2**Description**

Measure the percentage of surface area involved in the patient's body

Timepoint

Beginning and end of the study

Method of measurement

Calculated with the formula of the percentage of surface area involved in the patient's body

3

Description

Measurement of redness of psoriasis rash

Timepoint

Beginning and end of the study

Method of measurement

Observation and clinical examination

Secondary outcomes

1

Description

Measurement of the rash protrusion of psoriasis

Timepoint

Beginning and end of the study

Method of measurement

Observation and clinical examination

2

Description

Measuring the extent of scaling of the psoriasis rash

Timepoint

Beginning and end of the study

Method of measurement

Observation and clinical examination

Intervention groups

1

Description

Intervention group: For patients in the intervention group, in addition to routine treatment (including the use of glycerin topical lotion 10% and 25 mg hydroxyzine tablets three times a day), 80 mg of Adalimumab ampoule subcutaneously to begin and then 40 mg a week later as subcutaneously and then 40 mg subcutaneously every two weeks for 16 weeks.

Category

Treatment - Drugs

2

Description

Control group: For patients in the control group, in addition to routine treatment (including topical 10% glycerin lotion and 25 mg hydroxyzine tablets three times daily), 20 mg of Methotrexate ampoule intramuscularly to start and then 10 mg intramuscularly one week later and then 10 mg intramuscularly will be administered every two weeks for 16 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital of Shahroud

Full name of responsible person

Dr. Marjan Talebi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hasan Emamian

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Vice chancellor for research; Shahroud University medical Sciences ,7th Tir squar, Shahroud

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice chancellor for research; Shahroud University medical and 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
Shahroud University of Medical Sciences
Full name of responsible person
Dr. Fateme Torabi
Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

No - There is not 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

No - There is not 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