# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

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

### Protocol summary

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

**Design**
This is a parallel randomized controlled clinical trial that will be performed on 92 patients with moderate to sever of 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 Ssciences and Health

**Country**
Iran (Islamic Republic of)

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+98 23 3239 5054

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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 sever of 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 Shahroud University of Medical Sciences

**Street address**
Shahroud University of Medical Sciences; 7 Tir squer, Shahroud

**City**
Shahroud

**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 sever 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
**Street address**
Imam Hossein Hospital., End Imam street., Shahroud , Iran
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marjan.talebi@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahroud University of Medical Sciences
**Full name of responsible person**
Dr. Mohammad Hasan Emamian
**Street address**
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**

General practitioner

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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**Full name of responsible person**

Dr.Mohammad Bagher Sohrabi

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**Latest degree**

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**Other areas of specialty/work**

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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