Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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Iran (Islamic Republic of)

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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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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Position

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Specialist

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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