

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Methotrexate alone vs. Methotrexate plus Betamethasone in the Treatment of Plaque-type Psoriasis

Protocol summary

Summary

This clinical trial study will accomplish in Alzahra hospital of Isfahan in 2016. The target population are patients with Plaque-type Psoriasis. The patients with inclusion criteria will be selected and randomly divided into two groups, in the manner that first one was drawn into one of the groups and other patient will be alternatively placed in the other group until the required sample size was obtained. In the first group 15 mg Methotrexate single dose weekly will be administered for 12 weeks and in the second group, same amount of Methotrexate plus 3 mg Betamethasone will be administered weekly for the same period. Patients will follow up during next 6 months after complete of treatment for detection of relapse and cure rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010312782N9**

Registration date: **2016-05-22, 1395/03/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-22, 1395/03/02

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2016-05-04, 1395/02/15

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Methotrexate alone vs. Methotrexate plus

Betamethasone in the Treatment of Plaque-type Psoriasis

Public title

Treatment of Plaque-type Psoriasis with Methotrexate plus Betamethasone

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with Plaque type of Psoriasis with involvement above 10% of body; Age range 15-65; No sensitivity to Methotrexate; No contraindication for Betamethasone use; No comorbidity with other Autoimmune diseases. Exclusion criteria: Patients resume from participation in the study; Impossibility of follow up of the patient due to various reason; Use of other treatment method during the study; Receive of other drugs during the study; Occurrence of drugs adverse reactions.

Age

From **15 years** old to **65 years** old

Gender

Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 50

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezarjerib
Street, Isfahan, Iran

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Isfahan

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1343478645

Approval date
2014-05-11, 1393/02/21

Ethics committee reference number
393179

Health conditions studied

1

Description of health condition studied
Psoriasis

ICD-10 code
L40.0

ICD-10 code description
Psoriasis Vulgaris

Primary outcomes

1

Description
Psoriasis Area Severity Index

Timepoint
Once any 2 Months

Method of measurement

Physical Examination

Secondary outcomes

empty

Intervention groups

1

Description
In Intervention group, 15 mg Methotrexate plus 3 mg
Betamethasone administred weekly up to 12 weeks.

Category
Treatment - Drugs

2

Description
In Control group 15 mg Methotrexate administred weekly
up to 12 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Hospital of Isfahan

Full name of responsible person
Yaser Askari

Street address
Alzahra Hospital, Soffe Avenue, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Isfahan University of Medical Sciences

Full name of responsible person
Ali Asilian

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Dermatology Department, Alzahra Hospital, Soffe
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Isfahan

Grant name

Grant code / Reference number

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

Title of funding source
Isfahan University of Medical Sciences

Proportion provided by this source
100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

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Position

Assistant of Dermatology

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Isfahan

Sharing plan**Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*