Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 wit Plaque-type Psoriasis. The patients with inclusion criteria will be selected and randomly divided in to 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 administrated for 12 weeks and in the second group, same amount of Methotrexate plus 3 mg Betamethasone will be administrated 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

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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 Plaue type of Psoriasis with involvement above 10% of body; Age range15-65; 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
City
Isfahan
Postal code
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
City
Isfahan

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 Avenue, Isfahan, Iran
City
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
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Person responsible for updating data

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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