

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3629 1510

##### Email address

mehrabi@mui.ac.ir

##### 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

##### 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 administered weekly up to 12 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

In Control group 15 mg Methotrexate administered 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

##### Street address

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****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Yaser Askari

**Position**

Assistant of Dermatology

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

Ali Mehrabi Koushki

**Position**

Epidemiologist

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Isfahan University of Medical Sciences

**Full name of responsible person**

Ali Asilian

**Position**

Dermatologist

**Other areas of specialty/work****Street address**

Dermatology Department, Alzahra Hospital, Soffe Avenue, Isfahan, Iran

**City**

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*