

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The efficacy of methotrexate plus pioglitazone in comparison with methotrexate alone in the management of patients with psoriasis vulgaris: a randomized controlled trial

Protocol summary

Summary

The aim of this single-blind single-center study is to evaluate the effect of pioglitazone in psoriasis. To do this, 40 patients with plaque type psoriasis who have indication for systemic therapy and not treated with phototherapy or any systemic agent in last 6 months are recruited. After preliminary evaluations (history, physical examination, CBC, blood biochemistry, etc.) those who have renal or hepatic disease, abnormal hepatic enzymes or any major systemic disease will be excluded. Then patients are assigned to one of the study groups (pioglitazone plus methotrexate or methotrexate alone) by block randomization. During the study if any of these major side effects occur, such as weight gain due to fluid retention and edema, decrease in Hb, WBC, or Plt, or significant increase in hepatic enzymes (more than 2.5 times of the baseline), the patient will be removed from the study. At 1, 2, 4, 6, 10 and 16 weeks patients are evaluated by psoriasis area and severity index (PASI) and dermatology life quality index (DLQI) scores and finally these two groups are compared and analyzed in terms of these scores.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202279149N1**
Registration date: **2012-05-26, 1391/03/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-05-26, 1391/03/06

Registrant information

Name

Soroush Daklan

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6641 8786

Email address

daklan@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-05-04, 1391/02/15

Expected recruitment end date

2012-08-05, 1391/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of methotrexate plus pioglitazone in comparison with methotrexate alone in the management of patients with psoriasis vulgaris: a randomized controlled trial

Public title

The effect of pioglitazone in psoriasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: plaque type psoriasis; Indication for systemic therapy; Phototherapy contraindicated; No

systemic therapy or phototherapy in last 6 months
Exclusion criteria: congestive heart failure; renal disease ; hepatic or pulmonary disease; abnormal hepatic enzymes; diabetes; pregnancy or lactation; potential for childbearing; any other major systemic diseases.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

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**

Tehran University of medical sciences

Street address

Tehran University of medical sciences, Ghods Avenue, Keshavarz Boulevard, Tehran

City

Tehran

Postal code**Approval date**

2011-12-03, 1390/09/12

Ethics committee reference number

90/130/1727/ ۵

Health conditions studied**1****Description of health condition studied**

psoriasis

ICD-10 code

L40.0

ICD-10 code description

Plaque psoriasis

Primary outcomes**1****Description**

psoriasis area and severity index (PASI)

Timepoint

at weeks 0, 6, 10, 16

Method of measurement

PASI meter

2**Description**

dermatology life quality index (DLQI)

Timepoint

at weeks 0,6,10,16

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

Hepatic enzymes

Timepoint

at weeks 0, 1,2,4,6,10,16

Method of measurement

blood biochemistry

2**Description**

complete blood cells (CBC)

Timepoint

at weeks 0,1,2,4,6,10,16

Method of measurement

automated analyzer (Automated blood count)

3**Description**

lipid profile

Timepoint

at weeks, 0, 6,10, 16

Method of measurement

Lipid Blood Tests

4**Description**

Bun and creatinine

Timepoint

at weeks 0,6,10,16

Method of measurement

blood biochemistry

5**Description**

urine analysis

Timepoint

at weeks 0,6,10,16

Method of measurement

Urine test strip

Intervention groups**1****Description**

oral methotrexate 7.5 to 15 mg per week for intervention group for 16 weeks, pioglitazone 30 mg per day orally for 16 weeks.

Category

Treatment - Drugs

2**Description**

oral methotrexate 7.5 to 15 mg per week for control group for 16 weeks.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Razi Hospital

Full name of responsible person

Soroush Daklan

Street address**City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Tehran University of Medical Sciences, Ghods Avenue, Keshavarz Boulevard, Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Soroush Daklan

Position

Resident of Dermatology

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

Razi hospital, Vahdat-e-eslami Square, Tehran, Iran

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Full name of responsible person

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

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Web page address**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