Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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/ د

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 t0 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 t0 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

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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