Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Study of efficacy and side effects of Pioglitazone in the treatment of plaque psoriasis vulgaris

Protocol summary

Summary

This study is a before-after clinical trial. The participants receive 30 mg/day of pioglitazone for 30 month (12 weeks) after evaluating inclusion and exclusion criteria and completing consent form. The PASI score and plaques specifications of patients are recorded monthly. In each visit the amount of scales, erythema and thickness of lesions and covering percentage are recorded into the checklists. Physical examinations and laboratory findings are entered in tables at each session.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903013862N2**
Registration date: **2010-06-08, 1389/03/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-06-08, 1389/03/18

Registrant information

Name

Farahzad Jababri Azad

Name of organization / entity

Mashahd University of Medical Scineces

Country

Iran (Islamic Republic of)

Phone

+98 51 1843 6626

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banihashemim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Council of Mashhad University of Medical Sciences

Expected recruitment start date

2007-09-26, 1386/07/04

Expected recruitment end date

2010-11-25, 1389/09/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of efficacy and side effects of Pioglitazone in the treatment of plaque psoriasis vulgaris

Public title

Study of efficacy and side effects of Pioglitazone in the treatment of psoriasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: new cases of plaque psoriasis which don’t received systematic treatment during last 3 months and for topical treatment last month, patients complete consent form and participate to study consciously. Exclusion criteria: patients who want to leave study deliberately, sensitive to pioglitazone or the same preparations, type one diabetes mellitus, pregnant or lactating women, below 18 years old, with severe hepatic problems (hepatitis, alcoholic or non alcoholic steatohepatitis, cirrhosis), severe cardiovascular disorders (NYHA CLASS III & IV), patients prevent pregnancy only by oral contraceptives, patients that have any of these following side effects during therapy: upper respiratory tract infections and sinusitis, edema and any indicative sign of heart failure, unwanted pregnancy, weight gain, anemia, leuckopenia, hematuria, jaundice and 3 times increment of hepatic enzymes

(ALT), any symptom which make patients to leave the study. Patients who used any of these drugs (Oral contraceptives, Gatifloxacin ,Insulin ,sulfunamides ,sulfunylureas, Thioridazine , Gemfibrozil).

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **26**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashad University of Medical Sciences

Street address
Central Building of Mashad University of Medical Sciences, Mashad, Iran

City
Mashhad

Postal code

Approval date
2007-10-26, 1386/08/04

Ethics committee reference number
286255

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 severity

Timepoint
monthly untill the end of 12 weeks

Method of measurement
PASI standard method

Secondary outcomes

1

Description
side effect

Timepoint
monthly untill end of 12 weeks

Method of measurement
Standard evaluation method for this disease

Intervention groups

1

Description
oral Pioglitazone 30 mg daily for 12 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Research center of skin disease and cutaneous leishmaniasis, Ghaem Hospital

Full name of responsible person
Dr Pouran Layegh, Dr sayed Rahman Movahed Ghodsi nia

Street address
Ghaem Hospital, Ahmad Abad Street

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Council of Mashhad University of Medical Sciences

Full name of responsible person
Vice chancellor for research of Mashhad University of Medical Sciences

Street address
Central Building of Mashad University of Medical Sciences

City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Council of Mashhad 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
Research center for skin disease and cutaneous leishmaniasis
Full name of responsible person
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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