

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

efficacy and safety of adding oral pioglitazone to standard treatment in lichen planopilaris

Protocol summary

Study aim

efficacy and safety of adding oral pioglitazone to standard treatment in lichen planopilaris

Design

Clinical trial with a control group, with parallel groups, three blinded, randomized, phase 3 on 30 patients.

Settings and conduct

The study population includes all patients with lichen planopilaris who refer to the dermatology clinic of the academic center.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- A disease that is resistant to treatment. It means that topical treatment along with at least 6 months of treatment has been ineffective. 2- Newly diagnosed patients who have not yet received treatment. 3- Patients who have been treated before and whose disease is still active. 4- Patients who, for any reason, have discontinued any previous medication 1 month before entering the study and have not used any other medication. 5- Patients between 18 and 50 years old
Criteria for not entering the study: 1- Pregnancy or breastfeeding 2- Wbc < 3000 3- Platelets < 100,000 4- Hemoglobin < 9 5- Excessive liver enzymes and active liver disease 6- Positive of viral hepatitis tests 7- Heart failure 8- Type 1 diabetes 9- Allergy to pioglitazone and methotrexate 10- Bladder cancer 11- Tissue edema

Intervention groups

In the group of methotrexate and pioglitazone, MTX dose test is first given in the amount of 15 mg by injection. 1 week later, CBC, liver enzymes and kidney function will be checked. If the tests are normal, the dose of 15 mg weekly systemically along with oral pioglitazone 15 mg daily is started for the patient. In the systemic methotrexate group, CBC, liver enzymes and kidney function are checked first, MTX is given as in the previous group.

Main outcome variables

Photography scoring score/LPPAI/Treatment groups/patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230415057912N1**

Registration date: **2023-12-07, 1402/09/16**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-07, 1402/09/16**

Update count: **0**

Registration date

2023-12-07, 1402/09/16

Registrant information

Name

Fereshteh Sherafat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 910 205 0355

Email address

dr.fereshteh69@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-01, 1402/02/11

Expected recruitment end date

2024-09-20, 1403/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

efficacy and safety of adding oral pioglitazone to standard treatment in lichen planopilaris

Public title

efficacy and safety of oral pioglitazone in treatment of lichen planopilaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

a disease that is resistant to treatment. It means that the treatment has been ineffective for at least 6 months. Newly diagnosed patients who have not yet received treatment. Patients who have been treated before and whose disease is still active. Patients who, for any reason, have discontinued any previous medication 1 month before entering the study and have not used any other medication at the time of the study. Patients between 18 and 50 years old

Exclusion criteria:

Pregnancy or breastfeeding wbc<3000 platelet<100000 hemoglobin<9 Liver enzymes that are too normal for reference and active liver disease Positive tests for viral hepatitis Heart failure Type 1 diabetes Allergy to pioglitazone and methotrexate Bladder cancer Tissue edema

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

By random allocation software, they are divided into two treatment groups with methotrexate and methotrexate and pioglitazone, and patients are selected by a simple random table.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient and the main executive of the plan, those who check the outcome, know that there are two treatment groups, but the assistant of the main executive knows who is in which group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Science

Street address

NO13, between 6 and 8 Vatan alley, East Haft Dast St ,Isfahan town

City

ISFAHAN

Province

Isfahan

Postal code

8164654933

Approval date

2023-04-14, 1402/01/25

Ethics committee reference number

IR.MUI.MED.REC.1402.040

Health conditions studied

1

Description of health condition studied

Lichen planopilaris

ICD-10 code

L66.1

ICD-10 code description

Lichen planopilaris

Primary outcomes

1

Description

Lichen Planopilaris Activity Index

Timepoint

Months 0, 2, 4, and 6 after starting the drug

Method of measurement

Handyscope dermatoskope (FotoFinder System GmbH, Bad Brinbach, Germany)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Methotrexate group with pioglitazone, test dose of MTX is given in the amount of 15 mg by injection. 1 week later, CBC, liver enzymes and kidney function will be checked. If the tests are normal,

the dose of 15 mg weekly systemically along with oral pioglitazone 15 mg daily is started for the patient. The minimum duration of treatment and follow-up is 6 months, and follow-up is done in months 0, 2, 4, and 6.

Category

Treatment - Drugs

2**Description**

Control group: Methotrexate group, the test dose of MTX is given in the amount of 15 mg by injection. 1 week later, CBC, liver enzymes and kidney function will be checked. If the tests are normal, a weekly dose of 15 mg is started for the patient. The minimum duration of treatment and follow-up is 6 months, and follow-up is done in months 0, 2, 4, and 6.

Category

Treatment - Drugs

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

Al-Zahra Hospital

Full name of responsible person

Mina Saber

Street address

Al-Zahra Hospital, Soffeh Blvd, Isfahan, Isfahan Province, Iran

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Fereshteh Sherafat

Position

Dermatology resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Fax**Email**

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Fereshteh Sherafat

Position

Dermatology resident

Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable