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
Isfehan
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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Esfahan

Province

Isfehan

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8174675731

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Email

alzahra@mui.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mina Saber

Street address

Isfahan university of medical sciences.,Hezar jerib Ave..

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Isfehan

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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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No.67,Joshaghani Ave.,Hakim nezami street.,Esfahan town

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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
Medical doctor
Other areas of specialty/work
Dermatology
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Person responsible for updating data

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Latest degree
Medical doctor
Other areas of specialty/work
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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