

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of the Effectiveness of Pioglitazone and Clobetasol and their possible adverse effect on patients with Lichen Planopilaris

Protocol summary

Study aim

Assessing the therapeutic effect of pioglitazone and clobetasol and their side effects in patients with lichen planopilaris

Design

phase three, two-arm parallel-group, single-blind randomized control trial. randomization was done using the Block randomization method.

Settings and conduct

The study is conducted in the dermatology clinic of Razi Hospital, Tehran. Enrolled patients are randomly assigned to the intervention or control group using the block randomization method. The patients will be assessed before starting the intervention and in the second, fourth, and sixth months. A dermatologist blinded to the study objectives visits the patients and evaluates the disease's severity using the lichen planopilaris activity index. A blinded statistician unaware of patients allocation will analyze the data.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 15 to 70 years, Written informed consent, no contraindications for pioglitazone (heart failure, COPD, kidney problem, liver problem, diabetes, allergy to pioglitazone), no pregnancy, and no recent use of OCP, Localized disease (the patient is not a candidate for systemic or immunosuppressive drugs), a new case with no previous history of drug use, or a known case with flare-up in whom the drug has not been started in the past three months. Exclusion Criteria: Unwillingness to participate, pioglitazone contraindications, pregnancy or OCP use, progressive multifocal disease (candidate for systemic or immunosuppressive treatment), a known case of LPP and a history of drug use in the past three months, taking drugs interacting with pioglitazone.

Intervention groups

The intervention and the control group received Pioglitazone 15 mg tablets daily and Clobetazone lotion 0.05 every night during the experiment, respectively.

Main outcome variables

the severity of lichen planopilaris based on lichen planopilaris activity index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210926052596N1**

Registration date: **2021-11-11, 1400/08/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-11, 1400/08/20**

Update count: **0**

Registration date

2021-11-11, 1400/08/20

Registrant information

Name

Amir peymanfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6640 5357

Email address

amirpeymanfar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Pioglitazone and Clobetasol and their possible adverse effect on patients with Lichen Planopilaris

Public title
Effect of Pioglitazone and Clobetasol

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 All patients between 15-70 years old with lichen planopilaris localized disease in which there was no need for systemic immunosuppressors no pregnancy or history of OCP consumption the patient a new case or was a known case who did not receive medication during the last three months no history of consuming a drug interaction with Pioglitazone no contraindication for Pioglitazone consumption such as diabetes mellitus, heart failure, hypersensitivity reaction to Pioglitazone Assign written informed consent
Exclusion criteria:
 Unwillingness to participate pioglitazone contraindications (diabetes, heart failure, COPD, kidney or liver disease, diabetes, allergy to pioglitazone) pregnancy or OCP use progressive multifocal disease (that is a candidate for systemic or immunosuppressive treatment) known case of LPP and a history of drug use in the past three months taking drugs interacting with pioglitazone.

Age
From **15 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
We will use a random-permuted block for randomization : We assign the different positions to groups 1 to 6. Then, we extract the numbers from the random numbers table and select any of the blocks assigned to these numbers. of note the block sizes were as follows: the first, third, fourth, and eighth blocks each have eight members. The second and fifth blocks have six and four members, respectively

Blinding (investigator's opinion)
Single blinded

Blinding description
The analyzer and the investigator are blind to the randomization grouping and drug administration.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Qods , Keshavars Blv,, Tehran Town

City

tehran

Province

Tehran

Postal code

1417613151

Approval date

2020-07-14, 1399/04/24

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.220

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

severity of lichen planopilaris based on lichen palonopilaris activity index

Timepoint

assessing the disease severity before starting the intervention and 2,4, 6 month after starting the medications

Method of measurement

Lichen planopilaris activity index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: those who received 1 tablet of Pioglitazone 15 mg every day till the end of the experiment

Category

Treatment - Drugs

2

Description

Control group: those who received topical Clobetasol lutions 0.05% on their lesions every night till the end of the experiment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic in Razi Hospital

Full name of responsible person

Amir Abbas peymanfar

Street address

Vahdat Eslami St., Vahdat Eslami Square, Razi Dermatology Hospital, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

vice chancellor for research, Qods st., Keshavarz blv., Tehran Town

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Amir Peymanfar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information is available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be accessible for academic researchers after
anonymization.

When the data will become available and for how long

After article publication, the Data will be accessible
forever

To whom data/document is available

all academic researchers in the field of medicine and
pharmacology

Under which criteria data/document could be used

Just for using in research fields and respecting the
original researchers in any referencing

From where data/document is obtainable

Contact with Dr peymanfar using the following email:
amirpeymanfar@yahoo.com

What processes are involved for a request to access data/document

Just an Email containing the main researchers' ID and the
primary subjective of their study.

Comments