

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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 Clobetasol 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 las 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

#### City

tehran

#### Province

Tehran

#### Postal code

1199663911

#### Phone

+98 21 5563 0553

#### Email

amirpeymanfar@yahoo.com

## 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

#### City

tehran

#### Province

Tehran

#### Postal code

1417613151

#### Phone

+98 21 6670 6142

#### Email

msahrai@tums.ac.ir

#### 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

#### Street address

No. 8, Hosseini Alley, Lashkarnezhad Alley, Valiasr st., Tehran Town

#### City

Tehran

#### Province

Tehran

#### Postal code

1196734841

#### Phone

+98 21 5536 7241

#### Email

amirpeymanfar@yahoo.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Vahide Sadat lajevardi

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Dermatology

**Street address**

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

**City**

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**Province**

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**Postal code**

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Vahide\_lajevardi@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Amir Abbas Peymanfar

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

No 8, Hosseini Alley, Lashkarnexhad Alley, Valiasr st.,  
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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**