

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Evaluation of the effect of adding oral minoxidil to standard anti-inflammatory therapy in the treatment of patients with lichen planopilaris

#### Protocol summary

##### Study aim

The aim of this study is to evaluate the effect of adding oral minoxidil to standard anti-inflammatory therapy in the treatment of patients with lichen planopilaris

##### Design

This study is a randomized clinical trial and patients are randomly divided into two groups of methotrexate and oral minoxidil with methotrexate by random allocation software

##### Settings and conduct

Two groups of 17 people are selected from the patients referred to the dermatology clinic. After the patient is examined for 3 (LPPAI score, photography and dermoscopy) and the results are recorded, treatment begins

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include patients between the ages of 18 and 65 who have just been diagnosed and have not yet received treatment. Patients who have previously been treated and whose disease is still active according to clinical and dermoscopic criteria Patients should have discontinued any previous systemic medication 1 month prior to enrollment and should not use any systemic or topical medications at the time of the study. Conditions for not entering the study are: Pregnancy or breastfeeding 2-leukocytes <3000 3-platelets <100000 4-Hemoglobin <9 5. Liver enzymes more than 2 times the reference limit 6. Positive hepatitis V tests 7- History of cardiovascular diseases and hypotension 8- History of arrhythmia (non-sinus rhythm in ECG)

##### Intervention groups

After obtaining the consent, one group will be treated with 15 mg of methotrexate weekly and the other group will be treated with 1 mg of minoxidil tablets with 15 mg of methotrexate for 6 months

##### Main outcome variables

Lichen planopilaris disease activity index is calculated and standard and dermoscopic general imaging is performed in all patients in months 0, 2, 4 and 6, then

the results of the two groups before and after treatment are compared

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220528055005N1**

Registration date: **2022-06-03, 1401/03/13**

Registration timing: **prospective**

Last update: **2022-06-03, 1401/03/13**

Update count: **0**

##### Registration date

2022-06-03, 1401/03/13

##### Registrant information

##### Name

Shaghayegh Dehghani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3668 8644

##### Email address

sh\_dehghanii@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-06-22, 1401/04/01

##### Expected recruitment end date

2023-12-22, 1402/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Evaluation of the effect of adding oral minoxidil to standard anti-inflammatory therapy in the treatment of patients with lichen planopilaris

## Public title

Effect of oral minoxidil in treatment of lichen planopilaris

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Newly diagnosed patients who have not yet received treatment. Patients who have previously been treated and whose disease is still active according to clinical and dermoscopic criteria Patients should have discontinued any previous systemic medication 1 month before entering the study and should not use any systemic or topical medication at the time of the study

### Exclusion criteria:

pregnancy or breastfeeding Leukocytes <3000 Platelets <100000 Hemoglobin <9 Liver enzymes more than 2 times the reference limit Positive for viral hepatitis tests History of cardiovascular disease and hypotension History of arrhythmia (non-sinus rhythm on ECG)

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **34**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients are randomly divided into two groups of methotrexate and oral minoxidil with methotrexate by random allocation software.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

### Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Ethics committee of IsfahanUniversity of Medical Sciences

#### Street address

No 38 ,second Alley, Mollasadra Ave

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8168613446

#### Approval date

2022-05-25, 1401/03/04

#### Ethics committee reference number

IR.MUI.MED.REC.1401.086

## Health conditions studied

### 1

#### Description of health condition studied

Lichen planopilaris

#### ICD-10 code

L66.1

#### ICD-10 code description

Follicular Lichen Planus

## Primary outcomes

### 1

#### Description

Lichen planopilaris activity index

#### Timepoint

Befor and after intervention

#### Method of measurement

Cheklis

### 2

#### Description

standardized global photography

#### Timepoint

Befor and after intervention

#### Method of measurement

Based on scoring by two dermatologist

### 3

#### Description

Dermoscopy

#### Timepoint

Befor and after intervention

#### Method of measurement

Chcklis

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: Methotrexate ( 15 mg/week orally in one day) will be administered in one group ( 17 patients) and for 6 months

### Category

Treatment - Drugs

## 2

### Description

Intervention group: Minoxidil 1 mg tablet in addition to methotrexate 15 mg weekly administered in the other group of 17 people for 6 months.

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Alzahra hospital

#### Full name of responsible person

Dr shaghayegh dehghani

#### Street address

Dermatology Department, Alzahra hospital, Sofe street ,Isfahan

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8168513446

#### Phone

+98 31 3668 8644

#### Email

sh\_dehghanii@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Dr Mozghan Mortazavi

#### Street address

Vice Chancellor for research, Isfahan University of Medical Sciences

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8168613446

#### Phone

+98 31 3668 8644

#### Email

sh\_dehghanii@yahoo.ccom

### 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

Dr Shaghayegh dehghani

#### Position

Dermatology resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Dermatology

#### Street address

Department of Dermatology ,Alzahra hospital, Sofe street

#### City

Isfahan

#### Province

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#### Postal code

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#### Phone

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#### 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

Dr shaghayegh dehghani

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Dermatology resident

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr shaghayegh dehghani

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**Latest degree**

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**Phone**

000983136688644

**Email**

sh\_dehghanii@yahoo.com

**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**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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