

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Cheklist

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

Chcklist

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Mozhgan Mortazavi

Street address

Vice Chancellor for research, Isfahan University of Medical Sciences

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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

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Person responsible for updating data

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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

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