

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the efficacy of topical cyclosporine versus clobetasol lotion in patients with lichen planopilaris (LPP) treated with hydroxychloroquine: a single-blinded randomized clinical trial

Protocol summary

Study aim

Comparing the effectiveness of topical cyclosporine with clobetasol lotion in the treatment of patients with lichen planopilaris treated with hydroxychloroquine

Design

A controlled, parallel, single-blinded, randomized, phase 2-3 clinical trial in 18 patients. Randomized with sealed envelopes.

Settings and conduct

Patients diagnosed with lichen planopilaris treated with hydroxychloroquine are randomly assigned to one of the following two groups: topical cyclosporine 2.5% once daily for 5 months and clobetasol lotion once daily for 5 months. Each patient is re-examined at 1, 3, 5, and 6 months after starting treatment, and at each session, in addition to clinical and dermoscopic imaging, disease severity is determined using LPPAI criteria. The physician evaluating the severity of disease and comparing the clinical and dermoscopic images, as well as the statistical expert, do not know which treatment group the patient is in.

Participants/Inclusion and exclusion criteria

inclusion criteria: patients between 13 and 60 years of age and a histopathologic diagnosis of lichen planopilaris. exclusion criteria: Topical or oral treatment in the last month The presence of serious concomitant diseases such as uncontrolled diabetes, uncontrolled hypertension, malignancies, retinal diseases

Intervention groups

group 1: topical cyclosporine, group 2: clobetasol lotion

Main outcome variables

Determining the severity of the disease based on LPPAI (lichen planopilaris activity index)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170809035597N3**

Registration date: **2022-11-19, 1401/08/28**

Registration timing: **prospective**

Last update: **2022-11-19, 1401/08/28**

Update count: **0**

Registration date

2022-11-19, 1401/08/28

Registrant information

Name

Azadeh Goodarzi

Name of organization / entity

Iran University of Medical Sciences (IUMS), Rasool

Akram hospital, Department of Dermatology

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-26, 1401/09/05

Expected recruitment end date

2022-12-26, 1401/10/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of topical cyclosporine versus clobetasol lotion in patients with lichen planopilaris (LPP) treated with hydroxychloroquine: a single-blinded randomized clinical trial

Public title

The effect of topical cyclosporine in lichen planus of the hair

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients between 13 and 60 years of age histopathologic diagnosis of lichen planopilaris

Exclusion criteria:

Topical or oral treatment in the last month The presence of serious concomitant diseases such as uncontrolled diabetes, uncontrolled hypertension, malignancies, retinal diseases

Age

From **13 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **18**

Randomization (investigator's opinion)

Randomized

Randomization description

After being selected by available method, patients are divided into two groups by simple randomization, so that among 18 sealed bags, one bag will be randomly selected for each patient. Each bag contains the letter a or b: a for topical cyclosporine and b for clobetasol lotion.

Blinding (investigator's opinion)

Single blinded

Blinding description

The physician who evaluates the severity of the disease and compares the clinical and dermoscopic images, as well as the statistical expert, do not know to which treatment group the patient belongs.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2021-09-19, 1400/06/28

Ethics committee reference number

IR.IUMS.FMD.REC.1400.428

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

disease severity

Timepoint

One, three, five and six months after the start of treatment

Method of measurement

based on LPPAI (lichen planopilaris activity index) criteria

Secondary outcomes

1

Description

physician satisfaction

Timepoint

One, three, five and six months after the start of treatment

Method of measurement

Based on the 5-point physician global assessment score using clinical and dermoscopic images

2

Description

patient satisfaction

Timepoint

One, three, five and six months after the start of treatment

Method of measurement

Based on the 5-point patient global assessment score

3

Description

tolerability

Timepoint

One, three, five and six months after the start of treatment

Method of measurement

Using a checklist (yes, no)

4

Description

adverse effects

Timepoint

One, three, five and six months after the start of treatment

Method of measurement

Using a checklist

Intervention groups

1

Description

Intervention group 1: Topical cyclosporine 2.5% once a day for 5 months

Category

Treatment - Drugs

2

Description

Intervention group 2: clobetasol lotion 0.05% once a day for 5 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Azadeh Goodarzi

Street address

Rasool Akram hospital, Niayesh avenue, Sattarkhan street, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Azadeh Goodarzi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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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

Not applicable