

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the simultaneous effect of oral administration of clobetasol lotion and cyclosporine with the clobetasol lotion alone in the treatment of lichen plano pilaris

Protocol summary

Study aim

The effect of cyclosporine alone on the treatment of lichen planulopathy

Design

The cases were selected randomly from among patients with Lichen Plano-Pillars referred to Razi Hospital

Settings and conduct

Patients in Razi Hospital respond to questioner's questions

Participants/Inclusion and exclusion criteria

All patients with lichen planulus disease

Intervention groups

A study was conducted to evaluate the efficacy of cyclosporine / clobetasol and the clovertaseol group alone, and finally, a comparison was made between the effects of these two groups.

Main outcome variables

regrowing of hair in areas of hair loss if the patient is at an early stage of the disease

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8803 2269

Email address

ensiehyousefi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-01, 1397/06/10

Expected recruitment end date

2019-01-05, 1397/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181112041620N1**

Registration date: **2019-03-12, 1397/12/21**

Registration timing: **retrospective**

Last update: **2019-03-12, 1397/12/21**

Update count: **0**

Registration date

2019-03-12, 1397/12/21

Registrant information

Name

ensieh yousefi Abdolmaleki

Scientific title

Comparison of the simultaneous effect of oral administration of clobetasol lotion and cyclosporine with the clobetasol lotion alone in the treatment of lichen plano pilaris

Public title

Effect of cyclosporine on hair loss of lichen planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with lichen plano pilaris disease at Razi Hospital
Age limits of 15 to 40 years

Exclusion criteria:

Must be at least one month from the initial referral of these patients to the hospital

Age

From **15 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

To conduct this research, referrals to Razi Hospital in Tehran who have Lpp disease, diagnosed as one month old and ranged from 15 to 70 years old, were randomly assigned 40 individuals individually And by hiding the drug using the spss analysis software.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this research, the method of double-blind study was used and the patients and primary investigators of the questionnaire were completely unaware of the treatment method.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Mulla Sadra Street- North Shirazi Ave. - East Saeb Street - No. 216

City

Tehran

Province

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Postal code

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Approval date

2018-08-21, 1397/05/30

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.341

Health conditions studied

1

Description of health condition studied

Lichen planopilaris

ICD-10 code

L67

ICD-10 code description

Hair color and hair shaft abnormalities

Primary outcomes

1

Description

Plano Polaris's patients percentage

Timepoint

60days

Method of measurement

Therapeutic questions from the patient

Secondary outcomes

1

Description

Patients may also experience minor problems such as scaling and atrophy due to drug use

Timepoint

30 days

Method of measurement

Random selection of patients and therapist's questions

Intervention groups

1

Description

A lotion of clobetasol as a nosebleed topical steroid once at 30 drops for at least six months

Category

Placebo

2

Description

Oral ciclosporin at a dose of 1 to 3 mg / kg daily plus 30 drops of topical clobetasol lotion every night for 6 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi's Hospital of Tehran

Full name of responsible person

Dr. Robabeh Abedini

Street address

hran - Vahdat Islami St. - Islamic Unity Square - Razi's

Death Row - Razi Skin Specialist Hospital

City

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Phone

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Email

razihospital@sina.tums.ac.ir

Web page address

Https://razihos.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Zohreh Ghodsi

Street address

Tehran, Keshavarz Blvd., Corner of Ghods St, Central
Office of Tehran 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

Tehran University of Medical Sciences

Proportion provided by this source

20

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

Ensiyeh Yousefi Abdolmaleki

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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Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

resident

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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

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