

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Clinical trial of comparison of methotrexate versus cyclosporine on disease activity index in patients with lichen planopilaris

Protocol summary

Study aim

The aim of this study is comparison of efficacy between methotrexate vs. cyclosporine on activity of lichen planopilaris.

Design

A phase two randomized clinical trial, two parallel groups taking two different types of drugs (cyclosporine and methotrexate), each group 16 patients and total sample size is 32

Settings and conduct

After taking consent of patients who attend to the clinic and have inclusion criteria, they randomly divided to two groups, in each group they start to take drugs for six months, and they will be visited in regular intervals.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Scalp involvement more than 10%, Local disease (<10% involvement) resistant to topical or systemic treatment; Exclusion criteria: pregnancy, lactation, Hb < 9mg/dl, wbc < 4000, plt < 100000, liver enzymes 3 times more than upper limit of normal, positive viral hepatic tests, renal failure, uncontrolled blood pressure, administration of another immunosuppressive or topical medication by other physicians, elevated serum creatinine

Intervention groups

After taking consent, methotrexate (15mg/week) in one group and cyclosporine (max 300 mg/day) in other one will be administered for 6 months.

Main outcome variables

Lichen planopilaris activity index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190717044256N1**

Registration date: **2019-08-30, 1398/06/08**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-30, 1398/06/08**

Update count: **0**

Registration date

2019-08-30, 1398/06/08

Registrant information

Name

Minoo Jelvan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2020

Email address

minoo.jelvan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison of methotrexate versus cyclosporine on disease activity index in patients with lichen planopilaris

Public title

The effect of methotrexate and cyclosporine on lichen planopilaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Scalp involvement more than 10% Local disease (<10%involvement) resistant to 3-month topical treatment or 6-months systemic treatment The patients should be stopped all systemic or topical medications at least one month before enrollment to the study

Exclusion criteria:
Pregnancy lactation Hb<9mg/dl Wbc<4000 Plt<100000
Liver enzymes 3 times more than upper limit of normal
Positive viral hepatic tests Renal failure Uncontrolled blood pressure Administration of another immunosuppressive or topical medication by other physicians Elevated serum creatinine >50% or >25% by lower doses of drug(25-50% over 2weeks)

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: 32

Randomization (investigator's opinion)
Randomized

Randomization description
patients who have inclusion criteria randomly are divided between two groups ; randomly the first patient belongs to the first group for taking cyclosporine and the second one starts to take methotrexate in second group. Theretofore the end of the study they will be divided between two groups one- to -one insofar each group reaches to 16 patients

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 Isfahan university of medical sciences

Street address

Hezarjarib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2018-05-30, 1397/03/09

Ethics committee reference number

IR.MUI.MED.REC.1397.068

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

Lichen planopilaris activity

Timepoint

Before and after 2,4,6 months after intervention

Method of measurement

Checklist of criteria in lichen planopilaris activity index ; Lichen planopilaris activity index is measured by this formula:LPPAI = (itch + pain + burn) / 3 + (scalp erythema + perifollicular erythema +perifollicular scale) / 3 + 2.5(pull test) + 1.5(spreading / 2)

2

Description

Standardized global photography

Timepoint

Before and after intervention

Method of measurement

Based on scoring by two dermatologists

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Methotrexate(15mg/week orally,in one day) will be administered in one group(16 patients) for six months

Category

Treatment - Drugs

2

Description

Intervention group: Cyclosporine(300mg/day orally),will be administered in one group(16 patients)for 6 months

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Minoo Jelvan,MD

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Sofe street

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Derm@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Shaghayegh Haghjoo

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vice chancellor for Research ,Isfahan unicersity of
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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

Minoo Jelvan,MD

Position

Dermatology resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Department of Dermatology, Alzahra hospital, Sofe
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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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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

In our research enough and appropriate information about patient's demographic data , analysis of before and after indices of LPPAI and global standardized photography will be published as our clinical report .

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available