

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Summary

Objective: The aim of this study is comparison of efficacy between methotrexate vs. hydroxychloroquine on activity of lichen planopilaris. 2) Design: This study is a randomized clinical trial. 3) Setting and conduct: The patients with lichen planopilaris in dermatology clinic will be randomly divided into two groups (15 patients in methotrexate group and 14 ones in hydroxychloroquine group). 4) Intervention: After taking consent, methotrexate (15 mg/week) in one group and hydroxychloroquine sulfate (400 mg/day) in the other one will be administered for 6 months. 5) Main outcome measures: Lichen planopilaris activity index (LPPAI) will be calculated and standardized global photography will be taken in all patients. Then, the aforementioned indices and the efficacy of medications after the intervention will be compared between the groups. 6) Participants: Inclusion criteria: Scalp involvement > 10% and no response to the previous 3-month topical or 6-month systemic medications; In the case of local involvement (<10% of scalp), resistance to the combination of topical and at least 6-month systemic therapy; the patients should be stopped all systemic medications at least 1 month before enrollment to the study. Exclusion Criteria are as follow: pregnancy or lactation; Hb < 9 mg/dl; WBC < 4000; platelet < 100000; liver enzymes > 2 times of upper limit of normal; and positive viral hepatic markers. Withdrawal criteria include no show up in follow-up visits; discontinuing the medication by patient; administration of another immunosuppressive or topical medication by other physician

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062822959N1**
Registration date: **2015-08-19, 1394/05/28**

Registration timing: na

Last update:

Update count: **0**

Registration date

2015-08-19, 1394/05/28

Registrant information

Name

Mina Saber

Name of organization / entity

Isfahan University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3669 5414

Email address

m_saber@mail.mui.ac.ir

Recruitment status

Not enough for processing

Funding source

This research was supported and funded by Isfahan University of Medical Sciences (Code: 392118).

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

empty

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

The effect of methotexate and hydroxychloroquine on lichen planopilaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Scalp involvement > 10% and no response to the previous 3-month topical or 6-month systemic medications; In the case of local involvement (<10% of scalp), resistance to the combination of topical and at least 6-month systemic therapy; the patients should be stopped all systemic medications at least 1 month before enrollment to the study. Exclusion Criteria are as follow: pregnancy or lactation; Hb < 9 mg/dl; WBC < 4000; platelet < 100000; liver enzymes > 2 times of upper limit of normal; and positive viral hepatic markers. Withdrawal criteria include no show up in follow-up visits; discontinuing the medication by patient; administration of another immunosuppressive or topical medication by other physician.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 24

Randomization (investigator's opinion)

Randomized

Randomization description**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

Isfahan University of Medical Sciences, Hezarjarib street, Isfahan, Iran

City

Isfahan

Postal code

73461-8147

Approval date

2015-02-25, 1393/12/06

Ethics committee reference number

394165

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

Before and after intervention

Method of measurement

Checklist

2**Description**

Standardized global photpgraphy

Timepoint

Before and after intervention

Method of measurement

Based on scoring by two deramtologist

Secondary outcomes

empty

Intervention groups**1****Description**

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

Category

Treatment - Drugs

2**Description**

Hydroxychloroquine sulfate (Two tablets daily that is equivalent to 400 mg) administered in the other group (14 patients) for 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Dr. Mina Saber

Street address

Dermatology Department, Alzahra hospital, Sofe street, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mehdi Nematbakhsh

Street address

Vice Chancellor for Research, Isfahan University Of Medical Science, Hezarjarib Street, Isfahan, Iran

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences and Health Services

Full name of responsible person

Dr. Mina Saber

Position

Resident of Dermatology

Other areas of specialty/work**Street address**

Department of Dermatology, Alzahra hospital, Sofe street, Isfahan, Iran

City

Isfahan

Postal code

8174645731

Phone

+98 31 3669 5414

Fax**Email**

m_saber@mail.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences and Health Services

Full name of responsible person

Dr. Mina Saber

Position

Resident of Dermatology

Other areas of specialty/work**Street address**

Department of Dermatology, Alzahra hospital, Sofe street, Isfahan, Iran

City

Isfahan

Postal code

8174645731

Phone

+98 31 3669 5414

Fax**Email**

m_saber@mail.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences and Health Services

Full name of responsible person

Dr. Mina Saber

Position

Resident of Dermatology

Other areas of specialty/work**Street address**

Department of Dermatology, Alzahra hospital, Sofe street, Isfahan, Iran

City

Isfahan

Postal code

8174645731

Phone

+98 31 3669 5414

Fax**Email**

m_saber@mail.mui.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty