Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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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

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Person responsible for updating data

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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