Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative efficacy study of oral methotrexate and oral prednisolone versus oral methotrexate in Lichen planopilaris patients

Protocol summary

Study aim
Comparative efficacy study of oral methotrexate and oral prednisolone versus oral methotrexate in Lichen planopilaris patients

Design
Randomized, double blinded, parallel group clinical trial

Settings and conduct
Patients with lichen planopilaris attending to Alzahra Hospital are randomly divided into two groups. patients in control group receive methotrexate 15 mg/week. patients in intervention group receive methotrexate with similar dose as well as pulse prednisolone 200 mg per week. patients are examined at base line, 2, 4 and 6 months and their LPPAI is recorded by a blind examiner and lab data is documented in first months every 2 weeks and then monthly. Standard photography is done at baseline and at month 6 and a blind investigator evaluates them using a 7-point scale.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with active Lichen planopilaris resistant to other systemic therapy or patients with progressive disease who doesn't have received any treatment for 3 months. exclusion criteria: Diabetes, active infection, abnormal liver enzymes, anemia, leukopenia, thrombocytopenia, severe hypertension, heart failure, pregnancy and lactation

Intervention groups
Control group: patients receiving oral methotrexate (15 mg per week) Intervention group: patients receiving oral methotrexate (15 mg per week) and pulse prednisolone (200 mg per week)

Main outcome variables
Pruritis, pain, soreness, erythema, peri follicular erythema, peri follicular scale anagen pull test spreading 7- point scales based on pre and post treatment photography

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190911044742N1**
Registration date: **2020-01-19, 1398/10/29**
Registration timing: **retrospective**

Last update: **2020-01-19, 1398/10/29**
Update count: **0**

Registration date
2020-01-19, 1398/10/29

Registrant information

Name
Farifteh Esfahanian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 5523 4893

Email address
farifteh_165@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-20, 1396/12/01

Expected recruitment end date
2018-08-23, 1397/06/01

Actual recruitment start date
2018-04-21, 1397/02/01

Actual recruitment end date
2018-12-06, 1397/09/15

Trial completion date
2019-06-05, 1398/03/15

Scientific title

Comparative efficacy study of oral methotrexate and oral prednisolone versus oral methotrexate in Lichen planopilaris patients

Public title
Effect of oral methotrexate and oral prednisolone in Lichen planopilaris

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Scalp involvement more than 10% (New cases and resistant to topical therapy cases) Localized scalp involvement (less than 10%) resistant to systemic and topical therapy

Exclusion criteria:
Pregnancy and lactation Hemoglobin < 9 mg/ dl Leukocyte < 4000 Platelet < 100000 Liver enzymes higher than 2 fold normal range Positive hepatitis viral test Diabetes Hypothyroidism and hyperthyroidism Severe hypertension Heart failure Active infection Nephropathy Peptic ulcer

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **28**
Actual sample size reached: **25**

Randomization (investigator's opinion)
Randomized

Randomization description
Individual randomization, using random number table Each patient will be assigned a number from 01 to 28. Then we randomly choose a spot on the random digit table. we use the first 2 digits of the numbers on the chart (since we have a population of 28 patients) and document the first 14 numbers that are less than 29. Patients with these numbers are allocated to control group. Patients with the next 14 numbers collected from the chart, are allocated to recive methotrexate and prednisolone. Patients are not aware of group allocation.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients receive different drugs but they are not aware of their intervention group. An investigator who examines patients and records data is not aware of patients' interventional group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan Univesity of Medical sciences

Street address
3th level,Aftab apartment bulding,Navid dead end,Yaghob jan alley,Nazar street,Esfahan

City
Isfahan

Province
Isfehan

Postal code
8175785994

Approval date
2019-08-28, 1398/06/06

Ethics committee reference number
IR.MUI.MED.REC.1398.307

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
Pruritis

Timepoint
Baseline and at 2,4,6 months

Method of measurement
Asking patient (Negative = 0 , + / - = 1 , + = 2 , ++ +++ = 3)

2

Description
Pain

Timepoint
Baseline and at 2,4,6 months

Method of measurement
Asking patient (Negative = 0 , + / - = 1 , + = 2 , ++ +++ = 3)

3

Description

soreness

Timepoint

Baseline and at 2,4,6 months

Method of measurement

Asking patient (Negative = 0 , + / - = 1 , + = 2 , ++ +++ = 3)

4

Description

Erythema

Timepoint

Baseline and at 2,4,6 months

Method of measurement

Examining patient (Negative = 0 , + / - = 1 , + = 2 , ++ +++ = 3)

5

Description

Peri follicular erythema

Timepoint

Baseline and at 2,4,6 months

Method of measurement

Examining patient (Negative = 0 , + / - = 1 , + = 2 , ++ +++ = 3)

6

Description

Peri follicular scale

Timepoint

Baseline and at 2,4,6 months

Method of measurement

Examining patient (Negative = 0 , + / - = 1 , + = 2 , ++ +++ = 3)

7

Description

Spreading

Timepoint

Baseline and at 2,4,6 months

Method of measurement

Examining patient (No Spreading = 0 Indeterminate = 1 Presence of Spreading = 2)

8

Description

Anagen pull test

Timepoint

Baseline and at 2,4,6 months

Method of measurement

Examining patient: No Anagen Hairs = 0 Presence of Anagen Hairs = 1

9

Description

7-point scale bases on pre treatment and post treatment photography

Timepoint

Base line and at 6 months

Method of measurement

scoring based on pretreatment and post treatment photographs: (Greatly decreased = -3Moderately decreased = -2Slightly decreased = -1No change = 0Slightly increased = +1Moderately increased = +2Greatly increased = +3Don’t know = Technical issues with the photographs did not for accurate evaluation)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Methotrexate 15 mg per week (2.5 mg tablets 6 number)

Category

Treatment - Drugs

2

Description

Intervention group: Methotrexate 15 mg per week and pulse prednisolone 200 mg per week (50 mg tablets 4 number)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Farahnaz Fatemi

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3th level,Aftab apartment bulding,Navid dead end,Yaghob jan alley,Nazar street,Esfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person
Shaghayegh haghjooye javanmard
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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
Farifteh Esfahanian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
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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
There isn't any more information.

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