Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Comparing the effectiveness of Methotrexate versus Azathioprine on disease activity index in Lichen planopilaris patients

Protocol summary

Study aim
Assessing the effectiveness of Methotrexate versus Azathioprine on disease activity index in Lichenplanopilaris patients
Design
Randomized double-blinded parallel clinical trial
Settings and conduct
All patients with diagnosis of Lichen planopilaris and meeting inclusion and exclusion criteria, referring to dermatology clinic, Alzahra University-affiliated Hospital of Isfahan. Each group will start its treatment and then will be assessed for cure and side effects 2, 4, and 6 months later.
Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with local disease that does not respond to topical treatment after one month Patients with extensive scalp involvement as the first line treatment. Patients should have discontinued any previous systemic medication 1 month prior to admission to the study. ages 18-65 Exclusion criteria: Pregnancy or lactation Leukocytes less than 3000 (leukopenia) Platelets less than 100000 Hemoglobin less than 9 Liver enzymes more than 2 time the reference limit Positive for viral hepatitis tests Consumption of Allopurinol
Intervention groups
A group of 16 patients treating with Methotrexate 15 mg/week; a group of 16 patients treating with Azathioprine 2 mg/kg/day
Main outcome variables
Lichen planopilaris activity index score; Dermoscopy score; Photography score

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191006045005N2**
Registration date: **2021-03-29, 1400/01/09**
Registration timing: **prospective**

Last update: **2021-03-29, 1400/01/09**
Update count: **0**
Registration date
2021-03-29, 1400/01/09

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-04-21, 1400/02/01
Expected recruitment end date
2021-09-23, 1400/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of Methotrexate versus Azathioprine on disease activity index in Lichen planopilaris patients

Public title
Assessing the effectiveness of Methotrexat versus Azathioprine on disease activity index in Lichen

planopilaris patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with local disease that does not respond to topical treatment after one month Patients with extensive scalp involvement as the first line treatment. Patients should have discontinued any previous systemic medication 1 month prior to admission to the study. Ages 18-65

Exclusion criteria:

Pregnancy or lactation Leukocytes less than 3000 (leukopenia of any etiology) Platelets less than 100000 Hemoglobin less than 9 Liver enzymes more than 2 time the reference limit Positive for viral hepatitis tests Consumption of Allopurinol

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are allocated into either the intervention or control group using a non-stratified block randomization method to keep an even randomization ratio of (1:1). Random Allocation Software is used by our expert analytics to determine the list and group of patients. He is blinded to the selection process and pre-and post-operative assessments. The block size will be equal and is set to 4, the sufficient and estimated sample size will be 32, then the allocation code is set to sequential. The analytics will use the output of software to determine the sequence and allocation of patients. Then each code is written on a non-transparent envelope and a paper is put in it in which the intervention or control is written on the paper. The series of the envelope will be according to the software's list and they will keep in a large box with a locker. The analytics has the key for the box and this box will be kept in his room which the analytics has its only key and has no windows. As the patients enrolled in the study sequentially, the analytics use the designated envelope. The mechanism of randomization and block size will not be revealed to the principal investigator and other involved physicians.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will conduct as double-blind manner. At the beginning for each patient, a summary of pathophysiology and common treatment paths will be clarified. Then they will sign the informed consent to be treated in any of our groups by chance. The patients and their dermatologists who are present in all follow-up visits at the clinic and supervising the follow-up sessions and evaluating variables of treatment and other involved physicians in the clinic will be blinded. Only another non-involved researcher purchase the drugs from pharmaceutical companies and assigns them to group A and B and give them to the physician without interfering in the selection process or contacting the patients.

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

IsfahanUniversity of Medical Sciences,Hezarjirib street,Isfahan,Iran

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8174673461

Approval date

2020-10-29, 1399/08/08

Ethics committee reference number

IR.MUI.MED.REC.1399.661

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 Index

Timepoint

Measurement of Lichen planopilaris Activity Index at the

beginning of the study (prior to treatment) and 2, 4, and 6 months after the treatment

Method of measurement

Using an oral questionnaire and clinical examination of patient for items in lichen planopilaris activity index

2

Description

Photography

Timepoint

Photography at the beginning of the study(prior to treatment) and 2,4 and 6 month after treatment.

Method of measurement

Professional camera for dermatologist

3

Description

Dermoscopy

Timepoint

Dermoscopy at the beginning of the study(prior to treatment) and 2,4 and 6 month after treatment.

Method of measurement

Handyscope fotofinder system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 16 patients, Methotrexate oral tablet (anti-neoplastic) made by Zahravi Pharmaceutical Co. 15 mg/week for 6 month.

Category

Treatment - Drugs

2

Description

Intervention group 2: 16 patients, Azathioprine oral tablet (2mg/kg/day) for 6 months from Ramopharmin Pharmaceutical Co.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

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Sponsors / Funding sources

1

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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

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Parisa Hajheidari
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Dissemination of data that has nothing to do with the personality and identity of the participants in the study and they are merely the consequences of study.
When the data will become available and for how long
Start the access period after the article is published.
To whom data/document is available
The data will only be available to approved academic researchers after their authentication by the relevant university.
Under which criteria data/document could be used
The data can only be used for research and writing review article.
From where data/document is obtainable
The author will be available via the email and university phone number mentioned in the article.
What processes are involved for a request to access data/document
Allows access to dataif found the data is requested for non-industrial and non-comercial use.
Comments