Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Efficacy of Tofacitinib and Mycophenolate Mofetil in the Treatment of Lichen Planopilaris

Protocol summary

Study aim
Comparison of the Efficacy of Tofacitinib and Mycophenolate Mofetil in the Treatment of Lichen Planopilaris

Design
This study will be conducted at Sina Hospital in Tabriz. Patients will be randomly assigned to two groups: the first group (n=15) will receive 5 mg of tofacitinib daily, and the second group (n=15) will receive oral mycophenolate mofetil at a daily dose of 2 g. The treatment duration will be 6 months, and patient response to treatment will be assessed at months 0 (baseline), 2, 4, and 6 using the Lichen Planopilaris Activity Index (LPPAI).

Settings and conduct
This study is a randomized clinical trial conducted at the Sina Educational-Treatment Center in Tabriz. Following the assessment of inclusion and exclusion criteria, participants will be randomly allocated into two intervention groups. The first group will receive Tofacitinib (5 mg daily), and the second group will receive oral Mycophenolate Mofetil (2 g daily). The treatment duration is 6 months, and the response to treatment will be assessed at months 0 (baseline), 2, 4, and 6 using the Lichen Planopilaris Activity Index (LPPAI) by the investigators.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18 and 65 years Definitive diagnosis of LPP based on clinical findings and biopsy Exclusion criteria: Pregnancy or lactation History of severe autoimmune, hepatic, or renal diseases

Intervention groups
This study will be conducted at Sina Hospital in Tabriz. The first group (n=15) will receive 5 mg of tofacitinib daily, and the second group (n=15) will receive oral mycophenolate mofetil at a daily dose of 2 g. The treatment duration will be 6 months, and patients will be assessed at months 0 (baseline), 2, 4, and 6 using the Lichen Planopilaris Activity Index (LPPAI).

Main outcome variables
Disease severity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190325043107N86**
Registration date: **2026-09-19, 1405/06/28**
Registration timing: **prospective**

Last update: **2026-09-19, 1405/06/28**
Update count: **0**

Registration date
2026-09-19, 1405/06/28

Registrant information
Name
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Name of organization / entity
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-10-06, 1405/07/14
Expected recruitment end date
2027-10-06, 1406/07/14
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Efficacy of Tofacitinib and Mycophenolate Mofetil in the Treatment of Lichen Planopilaris

Public title
Comparison of the Efficacy of Tofacitinib and Mycophenolate Mofetil in the Treatment of Lichen Planopilaris

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 and 65 years Definitive diagnosis of LPP based on clinical findings and biopsy

Exclusion criteria:
Pregnancy or lactation History of severe autoimmune, hepatic, or renal diseases

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

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, with a sample size of 75, participants will be assigned to three groups using permuted block randomization. A block size of four will be employed, utilizing all possible combinations, including: Block 1 (BBAA), Block 2 (AABB), Block 3 (ABAB), Block 4 (BABA), Block 5 (ABBA), and Block 6 (BAAB). To accommodate 75 participants, 19 blocks will be generated using Random Allocation Software, with blocks randomly selected from numbers 1 to 6. For instance, if block 6 and block 2 are selected sequentially, the allocation sequence will be BAABAABB, assigning individuals to Intervention Group (A) Control Group (B). To ensure allocation concealment, the randomization list will be prepared and numbered by an independent researcher who is not involved in patient recruitment or assessment. The assignments will be placed in sequentially numbered, opaque, sealed envelopes (SNOSE). The study investigator will open the envelopes in numerical order only after a patient has been formally enrolled and their code has been recorded, ensuring that the allocation sequence remains unpredictable.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, to ensure proper patient blinding, the medications for groups A and B will be prepared in identical appearance, color, packaging, and administration method, making them indistinguishable to participants. Each medication will be labeled with a unique code (A or B), known only to an independent researcher who is not involved in patient recruitment or evaluation. The envelopes containing the coded medication will be provided to the study investigator in sequential order, without any indication of treatment type. Consequently, both patients and the investigator will remain unaware of group allocation, thus maintaining a practical and effective double-blind design throughout the trial.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Imam Reza Hospital, Azadi Ave

City
Tabriz

Province
East Azarbaijan

Postal code
5165665631

Approval date
2026-08-09, 1405/05/18

Ethics committee reference number
IR.TBZMED.REC.1405.320

Health conditions studied

1

Description of health condition studied
Lichen Planopilaris Activity Index

ICD-10 code
L66.1

ICD-10 code description
Lichen planopilaris

Primary outcomes

1

Description
Lichen Planopilaris Activity Index

Timepoint
Patients will be assessed at two time points: at baseline

(before the intervention) and 3 months post-intervention.

Method of measurement

Lichen Planopilaris Activity Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group will receive 5 mg of Tofacitinib orally on a daily basis. The efficacy of this treatment will be assessed at predefined time points using the Lichen Planopilaris Activity Index (LPPAI), which quantifies clinical symptom changes (such as pruritus and pain) and physical examination findings.

Category

Treatment - Drugs

2

Description

Control group: This group will receive 2 g of oral Mycophenolate Mofetil daily. Similar to the first group, treatment response will be monitored at scheduled intervals using the Lichen Planopilaris Activity Index (LPPAI) to accurately measure the improvement of clinical symptoms and physical examination findings.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Faegheh Sheykhalizade Nobar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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