Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the Effectiveness of Upadacitinib and Hydroxychloroquine as Standard Treatment in Lichen Planus Patient

Protocol summary

Study aim
Evaluation of the Effectiveness of Upadacitinib in Lichen Planus

Design
A clinical trial with a control group, with parallel groups, double-blinded, randomized, phase 3 on 32 patients. Random Allocation software is used for randomization.

Settings and conduct
This study will be conducted on patients with lichen planus who refer to the dermatology clinics of Shiraz University of Medical Sciences. Patients will be randomly divided into two intervention and control groups. The design will be outcome assessor blind.

Participants/Inclusion and exclusion criteria
The inclusion criteria will be patients older than 16 years of age, weighing more than 40 kg, with cutaneous involvement of lichen planus and eGFR >60 , who are referred to the Dermatology Clinic of Shiraz University of Medical Sciences as newly diagnosed cases and have not received any topical or systemic treatment for lichen planus prior to enrollment in the study. The exclusion criteria will include patients with oral, nail, genital, or hair involvement of lichen planus; pregnant or breastfeeding women; evidence of renal or hepatic failure; a history of CVA, MI, DVT, PTE, or PUD; leukemia, lymphoma, or bone marrow failure; glucose-6-phosphate dehydrogenase (G6PD) deficiency; retinopathy; neuropsychiatric disorders; lymphopenia; or leukopenia.

Intervention groups
Patients in the intervention group will receive the oral drug Opadacitinib Damonzia 15 mg (Kobel Daru Company) daily for 3 months.

Main outcome variables
Lichen Planus Activity and Damage Index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150825023753N31**
Registration date: **2026-10-30, 1405/08/08**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-30, 1405/08/08**
Update count: **0**

Registration date
2026-10-30, 1405/08/08

Registrant information

Name
Mohammad Mahdi Parvizi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3212 5592

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parvizim@sums.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-07, 1405/07/15

Expected recruitment end date
2027-03-06, 1405/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the Effectiveness of Upadacitinib and Hydroxychloroquine as Standard Treatment in Lichen Planus Patient

Public title
Evaluation of the Effectiveness of Upadacitinib in Lichen Planus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with newly diagnosed lichen planus by a dermatologist who have not previously received any topical or systemic treatment. Patients over 16 years of age Weight more than 40 kg Glomerular filtration rate (GFR) over 60
Exclusion criteria:
patients with Oral, nail, genitalia and hair involvements of lichen planus pregnant or nursing mothers evidence of renal or hepatic failure ,CVA ,MI ,DVT ,PTE ,PUD ,leukemia ,lymphoma, bone marrow failure,G۶PD deficiency ,retinopathy ,neuropsychiatric diseases ,lymphopenia , leucopenia
Age
From **16 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be divided into two groups using a permuted random blocking method of a size of 4, creating a randomization table by Random Allocation Software version ۱.۰.۰ . Moreover, dark envelopes will be used for random allocation concealment.
Blinding (investigator's opinion)
Single blinded
Blinding description
Because the intervention cannot be masked (due to the dissimilarity of the drugs upadacitinib and hydroxychloroquine), blinding is not possible for the patient. Given the type of intervention, it is preferable that one of the investigators in the study be blind to assess the side effects of the case group (especially in the upadacitinib group). Therefore, the attending supervisor will be the patient's care provider and is not blind, but the investigator, outcome assessor (who does not know the type of drug the patients are taking, and the study is conducted as a blind outcome assessor).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand blv., Shiraz, Fars, Iran
City
shiraz
Province
Fars
Postal code
14336 - 71348
Approval date
2026-09-06, 1405/06/15
Ethics committee reference number
IR.SUMS.MED.REC.1405.253

Health conditions studied

1

Description of health condition studied
lichen planus
ICD-10 code
L43
ICD-10 code description
Lichen planus

Primary outcomes

1

Description
Lichen Planus Activity and Damage Index
Timepoint
Before the intervention and 2 and 3 months later
Method of measurement
Lichen Planus Activity and Damage Index (LiPADI)

Secondary outcomes

1

Description
Intensity of itching
Timepoint
At the beginning of the study and 2 and 3 months later
Method of measurement
The visual analogue scale (VAS)

2

Description
Patient's satisfaction
Timepoint
At the beginning of the study and 2 and 3 months later

Method of measurement
Patient global assessment (PGA)

3

Description
General assessment of the doctor
Timepoint
At the beginning of the study and 2 and 3 months later
Method of measurement
Physician Global Assessment (PGA)

Intervention groups

1

Description
Intervention group: A group that receives the oral drug Opadacitinib Damonzia 15 mg (Kobel Daru Company) daily for 3 months.
Category
Treatment - Drugs

2

Description
Control group: This group will receive oral hydroxychloroquine (200 mg; Abidi Pharmaceutical Company, Iran) twice daily for 3 months as standard treatment for lichen planus.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi Hospital, Shiraz
Full name of responsible person
Mehdi Ghahartars
Street address
Shiraz - Zand Street - Shahid Faghihi Hospital
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7134846114
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mghahar@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr hamid mohamadi
Street address
Research vice, Shiraz University Of Medical Sciences, Zand street, Shiraz
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mohamadi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
milad falahzadeh
Position
Dermatology Resident
Latest degree
Medical doctor
Other areas of specialty/work
dermatology
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mehdi Ghahartars

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
dermatology

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The Dermatology Department of Faghihi Hospital, Zand Street,Shiraz

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Person responsible for updating data

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Full name of responsible person
Mohammad Mahdi Parvizi

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Traditional Medicine

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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
Demographic data and the result of the clinical trial

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
The data will be accessible to researchers working at academic and scientific institutions as well as those employed in the industry

Under which criteria data/document could be used
After the publication of the article based on the clinical trial, it will be possible to share the data. The recipients of the data can use the data by obtaining permission from the project managers. The managers of this project will allow the data to be used in secondary data analysis studies and systematic reviews.

From where data/document is obtainable
Data requesters can submit their request by sending an email to each of the administrators that their names and emails have been entered into this system.

What processes are involved for a request to access data/document
Data requesters can submit their request by sending an email to each of the administrators that their names and emails have been entered into this system.

Comments