Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the Effectiveness of Baricitinib with Hydroxychloroquine in Improving Cutaneous Manifestations in Lichen Planus Patients

Protocol summary

Study aim
Comparison of Efficacy Baricitinib and Hydroxychloroquine in Cutaneous Lichen planus

Design
Two arm parallel group randomised controlled clinical trial with blinded investigator and outcome assessment, phase 3 on 32 patients.We use Random Allocation Software for randomisation.

Settings and conduct
Control Group (16 cutaneous Lichen planus patients) will be treated with Hydroxychloroquine 200mg every 12 hours for 3 months. Intervention Group (16 cutaneous Lichen planus patients) will be treated with Baricitinib 4 mg Daily for 3 months.Clinical and laboratory evaluations will be done at the Beginning of the Study (before starting the Intervention) , 2,and 3 months after starting medicine at Shahid Faghihi Hospital.Investigator and outcome assessor will be not aware of therapeutic methods of the patients, and Trial will be investigator blind.

Participants/Inclusion and exclusion criteria
Inclusion Criteria:Over 16 Years Old, Lichen Planus Patients Who have Cutaneous Manifestations, Glomerular Filtration Rate More than 60 Exclusion Criteria:Pregnant Mothers, Lactating Mothers, Hepatic Failure, Renal Failure, Treated with Topical or Systemic Steroid 1 Year Before the Study, Past History of Cerebrovascular Attack, Past History of Myocardial Infarction, Past History of Deep Vein Thrombosis, Past History of Pulmonary Thromboembolism, Past History of Peptic Ulcer Disease, Past History of leukemia, Past History of lymphoma, Past History of Bone Marrow Failure, Past History of G6PD Deficiency, Past History of Retinopathy, Past History of Neuropsychiatric Diseases, Past History of lymphopenia, Past History of leucopenia, Patient Reluctance

Intervention groups
Intervention group: Tablet Baricitinib 4 mg (Arena Haiat Company) Daily for 3 months Control group: Tablet Hydroxychloroquine 200mg every 12 hours (Amin Company) for 3 months

Main outcome variables
Severity of Pruritis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241025063490N1**
Registration date: **2024-11-15, 1403/08/25**
Registration timing: **prospective**

Last update: **2024-11-15, 1403/08/25**
Update count: **0**

Registration date
2024-11-15, 1403/08/25

Registrant information

Name
Hossein Kargar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3484 6114

Email address
hosseinkargar@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-01-18, 1403/10/29

Expected recruitment end date
2026-01-10, 1404/10/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Baricitinib with Hydroxychloroquine in Improving Cutaneous Manifestations in Lichen Planus Patients

Public title

Effect of Baricitinib in Treatment of Lichen Planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Over 16 Years Old Lichen Planus Patients Who have Cutaneous Manifestations Glomerular Filtration Rate More than 60

Exclusion criteria:

Pregnant Mothers Lactating Mothers Hepatic Failure Renal Failure Treated with Topical or Systemic Steroid 1 Year Before the Study Past History of Cerebrovascular Attack Past History of Myocardial Infarction Past History of Deep Vein Thrombosis Past History of Pulmonary Thromboembolism Past History of Peptic Ulcer Disease Past History of leukemia Past History of lymphoma Past History of Bone Marrow Failure Past History of G6PD Deficiency Past History of Retinopathy Past History of Neuropsychiatric Diseases Past History of lymphopenia Past History of leucopenia Patient Reluctance

Age

From **16 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Random Number Table with Blocks of Four was Made by Replacement Block Method with Random Allocation Software. Patients Codes will be Put in Dark Envelopes to Hide Random Sequence, and Patients will Enter the Trial in Order of Number. Patients,Doctor, and Resident will not Decide About the Type of Interventions and Patients will be Put in Case and Control Groups Based on Random Number Table.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to Dissimilarity of Baricitinib and Hydroxychloroquine, Intervention is Unmaskable, so Blinding is not Possible for Patients.Moreover, One of the Researchers of the Trial Must not be Blind Because of the Type of Intervention to Check Complications of Case Group.so, Supervising Professor will be Care Provider and He Will not be Blinded, but Resident(Outcome Assessor, Investigator) Will not be Aware of the Type of Medicine, and Trial Will be Done as Investigator Blind Trial.

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

Shahid Faghihi Hospital , Near Shiraz University School of Medicine , Across the Shahid Faghihi Street , Karim Khan Zand Boulevard

City

Shiraz

Province

Fars

Postal code

7134846316

Approval date

2024-09-25, 1403/07/04

Ethics committee reference number

IR.SUMS.MED.REC.1403.427

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

Severity of Pruritis

Timepoint

Evaluation of Severity of Pruritis at the Beginning of the Study (before starting the Intervention) , 2,and 3 months after starting Baricitinib

Method of measurement

Numerical Visual Analogue Scale(0-10)

Secondary outcomes

1

Description
Time it takes to Respond to Treatment
Timepoint
Evaluation of Response to Treatment at the Beginning of the Study (before starting the Intervention) , 2,and 3 months after starting Baricitinib
Method of measurement
Time it takes to Respond to Treatment (by Weeks)

2

Description
Physician Global Assessment
Timepoint
Physician Global Assessment at the Beginning of the Study (before starting the Intervention) , 2,and 3 months after starting Baricitinib
Method of measurement
Physician Global Assessment Table

3

Description
Lichen planus Activity and Damage Index
Timepoint
Lichen planus Activity and Damage Index at the Beginning of the Study (before starting the Intervention) , 2,and 3 months after starting Baricitinib
Method of measurement
Lichen planus Activity and Damage Index Table

4

Description
Patient Satisfaction
Timepoint
Evaluation of Patient Satisfaction at the Beginning of the Study (before starting the Intervention) , 2,and 3 months after starting Baricitinib
Method of measurement
Numerical Visual Analogue Scale (0-10)

Intervention groups

1

Description
Intervention group: Tablet Baricitinib 4 mg (Arena Haiat Company) Daily for 3 months
Category
Treatment - Drugs

2

Description
Control group: Tablet Hydroxychloroquine 200mg every 12 hours (Amin Company) for 3 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi Hospital
Full name of responsible person
Farzad Homayoonfar
Street address
Shahid Faghihi Hospital , Near Shiraz University School of Medicine , Across the Shahid Faghihi Street , Karim Khan Zand Boulevard
City
Shiraz
Province
Fars
Postal code
7134846316
Phone
+98 71 3212 5526
Email
hosseinkargar@sums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Parvaneh Sadeghi
Street address
Shiraz University School of Medicine , Across the Shahid Faghihi Street , Karim Khan Zand Boulevard
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3235 7282
Email
vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
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

Hossein Kargar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Shahid Faghihi Hospital , Near Shiraz University School of Medicine , Across the Shahid Faghihi Street , Karim Khan Zand Boulevard

City

Shiraz

Province

Fars

Postal code

7134846316

Phone

+98 71 3235 1087

Email

hosseinkargar@sums.ac.ir

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

Street address

Shahid Faghihi Hospital , Near Shiraz University School of Medicine , Across the Shahid Faghihi Street , Karim Khan Zand Boulevard

City

Shiraz

Province

Fars

Postal code

7134846316

Phone

+98 71 3235 1087

Email

Mghahar@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hossein Kargar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Shahid Faghihi Hospital , Near Shiraz University School of Medicine , Across the Shahid Faghihi Street , Karim Khan Zand Boulevard

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Phone

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Email

hosseinkargar@sums.ac.ir

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

Total Data will be Shareable after Making Patient Unidentifiable ,and the Trial will be completed.

When the data will become available and for how long

The Start of the Access Period will be since 6 months after Publishing the Results,and it will be continued for unlimited Time Frame.

To whom data/document is available

Data will be available for Investigators employed in Scientific, Academic, and Industrial Institutions.

Under which criteria data/document could be used

Investigator will be able to use Data for Meta-Analysis, and comparison of Different Therapeutic Methods.

From where data/document is obtainable

Investigators can send Message to hoseinkargar7@gmail.com ,or 00989211230998 to access Data. Responder Name:Dr.Hossein Kargar

Address:Shahid Faghihi Hospital , Near Shiraz University School of Medicine , Across the Shahid Faghihi Street , Karim Khan Zand Boulevard

What processes are involved for a request to access data/document

Requests for Legal Scientific, Academic, and Industrial Actions will be responded in 2 Months, and Data will be made Available for Investigators.

Comments