

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

studying the therapeutic effect of baricitinib and its side effects and comparing it with clobetasol in LPP (Lichen Plano Pilaris)

Protocol summary

Study aim

studying the therapeutic effect of baricitinib and its side effects and comparing it with clobetasol solution in the treatment of lichen planopilaris patients referred to Razi Hospital in 2023-2024

Design

A clinical trial with a control group, with parallel groups, three blinded, randomized, phase 3 on 44 patients (22 cases in the intervention group and 22 men in the control group). The rand function of Excel software was used for randomization.

Settings and conduct

This study will be conducted in Razi skin hospital and four visits for each patient at intervals of two months from each visit (start of the study, months 2, 4 and 6) with three blind groups (patients, researcher, data collector) , and analyst people).

Participants/Inclusion and exclusion criteria

Patients with lichen planopilaris between the ages of 15 and 70 who enter the plan with informed consent and do not have a prohibition to receive baricitinib or clobetasol and do not take drugs that interfere with these two drugs. They are not pregnant or lactating, and they are not taking contraceptives, and in terms of the severity of the disease and the speed of its spread, they are not candidates for other drugs.

Intervention groups

Intervention group: treatment with baricitinib tablets 4 mg daily Control group: treatment with clobetasol solution 0.05% daily

Main outcome variables

The percentage of reduction in LICHEN PLANOPILARIS ACTIVITY INDEX score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221101056374N1**

Registration date: **2022-11-15, 1401/08/24**

Registration timing: **prospective**

Last update: **2022-11-15, 1401/08/24**

Update count: **0**

Registration date

2022-11-15, 1401/08/24

Registrant information

Name

Fateme Ghaseminia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 350 1258

Email address

f.ghaseminia@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2024-03-14, 1402/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

studying the therapeutic effect of baricitinib and its side effects and comparing it with clobetasol in LPP (Lichen Plano Pilaris)

Public title

studying the therapeutic effect of baricitinib and its side effects in LPP (Lichen Plano Pilaris)		After each patient was visited by the health care providers and the treatment was continued or changed for them (according to the discretion of the health care providers, who are aware of the study and the patient's treatment group and were not blinded), each patient went to the data collection officials (individuals who evaluate the patient to determine the disease activity index and record related information) will be that these data collectors will not know what treatment the patient is undergoing (they are blinded) and those who analyze the data and the Data Safety and Monitoring Committee and those who prepare the draft of the article are blinded to the study in the same way and considering that they do not know which treatment group each data belongs to.	
Purpose	Treatment	Placebo	Not used
Inclusion/Exclusion criteria	Inclusion criteria: Age between 15 and 70 years Acceptance of all provisions of informed consent regarding the plan Absence of contraindications for baricitinib use, including chronic renal failure with GFR below 30, severe liver failure, sensitivity to baricitinib, severe anemia with hemoglobin below 8, lymphopenia with an absolute lymphocyte count below 500, or neutropenia with an absolute neutrophil count below 1000, pregnancy and breastfeeding Not being pregnant and not taking OCP Severe and expanding multifocal disease that is a candidate for receiving systemic medication according to the opinion of the main executive of the plan. Not taking drugs that interact with baricitinib The patient's consent to enter the plan Exclusion criteria: For any reason, the patient does not agree to enter the plan For any reason, the patient does not agree with the provisions of informed consent in the plan Contraindications to baricitinib use include chronic renal failure with GFR below 30, severe liver failure, sensitivity to baricitinib, severe anemia with hemoglobin below 8, lymphopenia with an absolute lymphocyte count below 500, or neutropenia with an absolute neutrophil count below 1000, pregnancy and breastfeeding Pregnancy or OCP consumption Local and limited disease that is not a candidate for receiving systemic and immunosuppressive drugs according to the opinion of the main executive of the plan. Taking drugs that interfere with baricitinib	Assignment	Parallel
Age	From 15 years old to 70 years old	Other design features	
Gender	Both	Secondary Ids	empty
Phase	3	Ethics committees	
Groups that have been masked	• Outcome assessor • Data analyser • Data and Safety Monitoring Board	1	
Sample size	Target sample size: 22	Ethics committee	
Randomization (investigator's opinion)	Randomized	Name of ethics committee	Ethics committee of Tehran University of Medical Sciences
Randomization description	Random assignment to intervention and control groups: Participants in this study based on the random sequence determined by the statistical software in the form of simple randomization and in such a way that each person has the same chance as the other participants in one of the two The control group (treatment group with local lotion of clobetasol) or intervention (treatment group with baricitinib oral tablet 4 mg) will be placed.	Street address	Tehran, Keshavarz Blvd., Corner of Qods St., Central Organization of the University, 6th Floor, Research and Technology Vice-Chancellor, Ethical Committee Secretariat
Blinding (investigator's opinion)	Double blinded	City	Tehran
Blinding description		Province	Tehran
		Postal code	1417613151
		Approval date	2022-10-30, 1401/08/08
		Ethics committee reference number	IR.TUMS.MEDICINE.REC.1401.576
		Health conditions studied	
		1	
		Description of health condition studied	lichen planopilaris
		ICD-10 code	12
		ICD-10 code description	Chapter XII Diseases of the skin and subcutaneous tissue(L00-L99)

Primary outcomes

1

Description

Percentage reduction of LICHEN PLANOPILARIS ACTIVITY INDEX score

Timepoint

At the beginning of the study (before the start of the intervention) and 2, 4 and 6 months after the start of the study

Method of measurement

Lichen planopilaris disease activity index questionnaire

Secondary outcomes

1

Description

aspartate aminotransferase

Timepoint

The beginning of the study (before the start of the intervention) and 2, 4, and 6 months after the start of the study

Method of measurement

blood test

2

Description

alanine aminotransferase

Timepoint

The beginning of the study (before the start of the intervention) and 2, 4, and 6 months after the start of the study

Method of measurement

blood test

3

Description

alkaline phosphatase

Timepoint

The beginning of the study (before the start of the intervention) and 2, 4, and 6 months after the start of the study

Method of measurement

blood test

4

Description

creatinine

Timepoint

The beginning of the study (before the start of the intervention) and 2, 4, and 6 months after the start of the study

Method of measurement

blood test

5

Description

blood urea nitrogen

Timepoint

The beginning of the study (before the start of the intervention) and 2, 4, and 6 months after the start of the study

Method of measurement

blood test

6

Description

complete blood count

Timepoint

The beginning of the study (before the start of the intervention) and 2, 4, and 6 months after the start of the study

Method of measurement

blood test

Intervention groups

1

Description

Intervention group: tablet baricitinib 4 miligram daily oral intake

Category

Treatment - Drugs

2

Description

Control group: clobetasol topical lotion 0.05% once daily ,topical

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Fateme Ghasemina

Street address

Vahdat Eslami St., Razi Hospital

City

tehran

Province

Tehran

Postal code

119963911

Phone

+98 913 350 1258

Email

f.ghasemina@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fateme Ghasemini

Street address

Vahdat Eslami St., Razi Hospital

City

tehran

Province

Tehran

Postal code

119963911

Phone

+98 913 350 1258

Email

f.ghasemini@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Fateme Ghasemini

Position

Specialist assistant (resident)

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Vahdat eslami street. Razi hospital

City

tehran

Province

Tehran

Postal code

119963911

Phone

+98 913 350 1258

Email

f.ghasemini@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fateme Ghasemini

Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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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