Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

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

Protocol summary

Study aim
studing 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)

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+98 913 350 1258

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

Public title

studing the therapeutic effect of baricitinib and its side effects in LPP (Lichen Plano Pilaris)

Purpose

Treatment

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

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

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.

Blinding (investigator's opinion)

Double blinded

Blinding description

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.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran, Keshavarz Blvd., Corner of Qods St., Central Organization of the University, 6th Floor, Research and Technology Vice-Chancellor, Ethical Committee Secretariat

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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 Ghaseminia
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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
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 Ghaseminia
Position
Specialist assistant (resident)
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Other areas of specialty/work
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Person responsible for updating data

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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