Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparison of efficacy and safety of low-dose naltrexone with placebo in lichen planopilaris: A randomized double-blinded clinical trial

Protocol summary

Study aim

The main objective is to evaluate the efficacy and complications of naltrexone in patients with lichen planopilaris through comparing the response to treatment based on changes in LPPAI scores and the frequency of reported drug-related side effects between study groups after 6 months. The secondary objective will be assessing the effect of naltrexone on ameliorating inflammation (through multiple ESR assays) in patients with lichen planopilaris.

Design

Two-arm parallel placebo group, triple-blinded, outcome assessment randomized trial

Settings and conduct

After randomization, baseline assessments including disease activity and ESR will be carried out in the Razi dermatology hospital clinic. Then patients will be given their drugs for the upcoming 2 months for a total duration of 6 months. At 2-month intervals, they will be visited for assessing disease activity, treatment tolerance and complications of treatment. They will be sampled for ESR as well. At the end of the 6 month period, the gathered data will be analyzed. All the assessments and the analysis will be carried out by blinded individuals other than principal investigators.

Participants/Inclusion and exclusion criteria

Patients with the diagnosis of lichen planopilaris will enter the study. Whom with circumstances that interfere with the use of naltrexone will be excluded.

Intervention groups

One group will receive clobetasol ointment plus low-dose oral naltrexone pills (3mg/day) for 6 months. The other group will receive clobetasol ointment plus placebo.

Main outcome variables

Disease activity by lichen planopilaris activity index score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180809040747N1**
Registration date: **2018-09-02, 1397/06/11**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-02, 1397/06/11**
Update count: **0**

Registration date

2018-09-02, 1397/06/11

Registrant information

Name

Fereshteh Salarvand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4424 8739

Email address

fsalarvand@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2020-04-03, 1399/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and safety of low-dose naltrexone with placebo in lichen planopilaris: A randomized double-blinded clinical trial

Public title
The effect of naltrexone in lichen planopilaris
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of Lichenplanopilaris (LPP) based on pathology
Exclusion criteria:
Burn-out lesions Any treatments for lichenplanopilaris within the last month History of drug addiction or alcohol abuse History of psychiatric disorders Willing to get or being pregnant Consumption of drugs interfering with naltrexone (e.g. opioid antagonists) Generalized cutaneous or mucosal lichen plan
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **34**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be assigned to any of two groups by 4-spot permuted blocks with 1:1 ratio
Blinding (investigator's opinion)
Triple blinded
Blinding description
Participants are blinded by using identical placebos (in shape, package, and flavor). The principal investigator who assesses efficacy and individuals who assess safety are also blinded to assignment. The analyzer is blinded.
Placebo
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 University of Medical Sciences Central Building, Qods Ave., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417614411
Approval date
2018-03-10, 1396/12/19
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1396.4753

Health conditions studied

1

Description of health condition studied
Lichen Planopilaris
ICD-10 code
L66.1
ICD-10 code description
Lichen planopilaris

Primary outcomes

1

Description
Lichen Planopilaris Acivity Index (LPPAI) Score
Timepoint
before intervention and 2, 4 , 6 months after intervention
Method of measurement
LPPAI Questionnair

Secondary outcomes

1

Description
Treatment tolerance
Timepoint
2, 4 and 6 months after intervention
Method of measurement
Interview

2

Description
ESR
Timepoint
Before intervention and 2, 4 and 6 months after intervention
Method of measurement
Lab kit

Intervention groups

1

Description
Intervention group: Oral tab naltrexone 3mg once a day at 1 hr before sleep plus topical Clobetasol ointment once at night for 6 months
Category
Treatment - Drugs

2

Description
Control group: Oral Tab Placebo once a day at 1 hr before sleep plus topical clobetasole ointment once a day at night for 6 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Dermatology Hospital
Full name of responsible person
Vahideh Lajevardi
Street address
Vahdat-e-Eslami Street
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1199663911
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razihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraeian
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research@tums.ac.ir
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
Fereshteh Salarvand
Position
Resident
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Person responsible for updating data

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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Patient dataset, all collected data will be shared.
When the data will become available and for how long
After the final report, the data will be available forever.
To whom data/document is available
For academic individuals and also for whom serve in the pharmaceutical business.
Under which criteria data/document could be used
The only criterion will be citing the name of principal investigators in resultant academic works.
From where data/document is obtainable
By contacting principal investigators via this email: f.salarvand89@gmail.com
What processes are involved for a request to access data/document
Sending the email by the requester including their academic position or business information
Comments