

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Aug 2026

### Comparison of the efficacy, safety, satisfaction and tolerability of oral N-acetyl cystein Vs oral Pentoxifylline in patients with Lichen planopillarar: A randomized controled clinical trial; assessor and analysed blinder

#### Protocol summary

##### Study aim

Efficacy, side effects, tolerability and satisfaction of treatment with pentoxifylline or N-acetylcysteine in patients with lichen planopillarar Compared with the control group

##### Design

one envelope will be randomly selected for each patient. The letters A, B or C are inserted inside each envelope. The control group will receive 0.05% topical clobetasol solution each night with at least 30 drops to the alopecia area. The other groups in addition to the above treatment will be treated with pentoxifylline 400 mg twice daily and N-acetylcysteine 600 mg twice daily, respectively. LPPAI in each group at the beginning of the study, two months later and 4 months after the start of treatment and changes from baseline to the end of the study between all three groups were analyzed and evaluated. Response to treatment will be achieved if we have a 25 to 85% reduction in the LPPAI system.

##### Settings and conduct

Rasoul Akram Hospital, Tehran

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent, Do not have serious internal disease, Aged between 15-70, No history of serious gastrointestinal problems, There is no accompanying disease on the treatment site, The initial general Lab data of the patient do not show a serious problem. Exclusion criteria: Receiving any treatment during the last month, Positive history of gastrointestinal cardiovascular disease and malignancies, Pregnant and lactating people, Consumption of any medication that interferes with the medications received in this study, Accompaniment of the disease with the generalized form of skin lichen planus or the form of mucosal erosion

##### Intervention groups

Clobetasol solution , Clobetasol solution+ pentoxifylline and Clobetasol solution+ N-acetylcysteine

##### Main outcome variables

Lichen planopillarar activity index, complications, tolerability, satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210208050292N1**

Registration date: **2021-04-02, 1400/01/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-04-02, 1400/01/13**

Update count: **0**

##### Registration date

2021-04-02, 1400/01/13

##### Registrant information

##### Name

Hossein Ahmadi Kahjoogh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3741 7015

##### Email address

hossein.ak31@yahoo.com

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2020-04-08, 1399/01/20

##### Expected recruitment end date

2022-03-20, 1400/12/29

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the efficacy, safety, satisfaction and tolerability of oral N-acetil cystein Vs oral Pentoxyphilline in patients with Lichen planopillaris: A randomized controled clinical trial; assessor and analysed blinder

**Public title**

Comparison of oral N-acetil cystein Vs oral Pentoxyphilline in patients with Lichen planopillaris

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Informed consent Do not have serious internal disease. Aged between 15-70 No history of serious gastrointestinal problems. There is no accompanying disease on the treatment site The initial general Lab data of the patient do not show a serious problem

**Exclusion criteria:****Age**From **15 years** old to **70 years** old**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**Target sample size: **30****Randomization (investigator's opinion)**

Randomized

**Randomization description**

A simple randomization method will be used to perform the randomization process. The patients will be divided into three groups using Cards or envelop shuffling method.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

All assessments and analyzes will be performed by blind people other than the main researchers.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Iran university of medical sciences

**Street address**

10th Alley, Niayesh Ave, 16th West Ave, Sahand Town

**City**

Maragheh

**Province**

East Azarbaijan

**Postal code**

5518937747

**Approval date**

2020-08-18, 1399/05/28

**Ethics committee reference number**

IR.IUMS.FMD.REC.1399.336

**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**

To facilitate statistical comparison of the study results, the lichen planopilaris activity index scoring system (LPPAI) introduced by Chiang in 2010 will be used. In this system, 8 signs and symptoms of the disease are scored, including Itching, burning, pain, erythema, pre-follicular erythema, pre-follicular scale, anagen pull test and disease spreading. each criteria will be scored from 0 to 3: Thus, 0: lack of sign/symptom, 1: the mild sign/symptom, 2: the moderate sign/symptom and 3: the severe sign/symptom. In anagen pull test, zero score shows the result is negative and it is positive when the score is one. In spreading score, zero score shows no spreading, 1: moderate spreading and 2: severe spreading. The total score according to the following formula will be 0 to 10: LPPAI (0 to 10) = (itching + burning + pain) / 3 + (scalp erythema + pre-follicular erythema + pre-follicular shell) / 3 + 2.5 (anagen pull test) + 1/5 (spreading / 2). The tolerability of the treatment will be measured by asking the patients (yes / no) and the satisfaction of the treatment will be evaluated by a Likert scoring. Patients will be asked about the possible side effects of the drugs used in each appointment session (basic visit, second and fourth month).

**Timepoint**

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

**Method of measurement**

Lichen planopilaris activity index score: A questionnaire for assessing the severity of lichen planopilaris disease, which was developed and reported in 2010 by Chiang. Complications: Patient response based on Likert scale. Tolerance: Patient response based on Likert scale. Satisfaction: Patient response based on Likert scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The intervention groups in addition to the control treatment will be treated with pentoxifylline 400 mg twice daily and N-acetylcysteine 600 mg twice daily, respectively. LPPAI in each group at the beginning of the study, two months later and 4 months after the start of treatment and changes from baseline to the end of the study between all three groups were analyzed and evaluated. Response to treatment will be achieved if we have a 25 to 85% reduction in the LPPAI system. The control group will receive 0.05% topical clobetasol solution each night with at least 30 drops to the alopecia area.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rasool Akram hospital

##### Full name of responsible person

Hossein Ahmadi Kahjoogh

##### Street address

Rasool Akram hospital, Maziar Mansoori Ave, Sattar khan Blvd

##### City

Tehran

##### Province

Tehran

##### Postal code

1445613131

##### Phone

+98 21 6435 1000

##### Email

hossein.ak31@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Seyed Abbas Motavallian

##### Street address

Iran university of medical science, Hemmat Exp

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۴۹۶۱۴۵۳۵

##### Phone

+98 21 86701

##### Email

PR@iums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Iran 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

Iran University of Medical Sciences

##### Full name of responsible person

Hossein Ahmadi Kahjoogh

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dermatology

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##### Province

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##### Fax

##### Email

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## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Hossein Ahmadi Kahjoogh

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**Latest degree**

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Hossein Ahmadi Kahjoogh

**Position**

Resident

**Latest degree**

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

They will be published on the scientific journals

**When the data will become available and for how long**

From 2022 onwards

**To whom data/document is available**

It will be accessible for everyone

**Under which criteria data/document could be used**

Raw data will not be published

**From where data/document is obtainable**

Scientific websites

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

By sending email to the researcher

**Comments**