

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparative Efficacy of Tacrolimus 0.1% vs flucinolone ointment in patients with cutaneous lichen planus

Protocol summary

Summary

This study is designed as a double blind clinical trial, and the purpose is to compare the efficacy of tacrolimus ointment 0.1 % with fluocinolone ointment in patients with cutaneous lichen planus. 50 patients as groups of 25 subjects will be enrolled from the patients referred to dermatology clinic with a diagnosis of lichen planus. The main Inclusion criteria are: patients older than 2 years and patients with histopathological diagnosis of lichen planus. The exclusion criteria are: sensitivity to medication and pregnant or lactating women. Tacrolimus ointment 0.1 % will be used in the first group and Fluocinolone ointment will be used to treat the second group. Patients will be treated for 12 weeks and they will be visited once a month during this period to follow healing and treatment effects. Patients healing will be defined as the loss of lesions (papules and plaques) and pruritus. Presence of post inflammatory hyperpigmentation is not incompatible with healing. After the treatment period, patients will be followed for 3 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407263566N4**

Registration date: **2014-08-02, 1393/05/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-02, 1393/05/11

Registrant information

Name

Hamide Azimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1540 6612

Email address

azimih@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2014-05-19, 1393/02/29

Expected recruitment end date

2014-06-19, 1393/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Efficacy of Tacrolimus 0.1% vs flucinolone ointment in patients with cutaneous lichen planus

Public title

Comparative Efficacy of Tacrolimus 0.1% vs flucinolone ointment in patients with cutaneous lichen planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with definite diagnose of lichen planus; patients older than 2 years. Exclusion criteria: the presence of other skin diseases; patients using medication that can cause drug-induced lichen planus; history of drug reaction to steroid or Tacrolimus; pregnant women and lactating mothers; mental retarded

or physically disabled patients.

Age

From 2 years old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Daneshgah Sq.

City

Tabriz

Postal code

Approval date

2014-05-18, 1393/02/28

Ethics committee reference number

9330

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

The recovery rate of lichen planus lesions

Timepoint

Monthly, up to 6 months

Method of measurement

Clinical observation

Secondary outcomes

1

Description

Treatment complication

Timepoint

Monthly, up to 6 months

Method of measurement

Clinical observation

Intervention groups

1

Description

In the first group Tacrolimus 1% cream will be applied 2 times daily to cover the entire lesion for 12 weeks.

Category

Treatment - Drugs

2

Description

In the second group flucinolone ointment will be applied 2 times daily to cover the entire lesion for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Sina Hospital

Full name of responsible person

Esmail Emami

Street address

Dermatology ward, Sina Hospital, Azadi Ave.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Ali Reza Ostad Rahimi

Street address

Vice chancellor for research, Tabriz University of

Medical Sciences, Daneshgah Avenue, Daneshgah Square

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Esmail Emami

Position

Resident of Dermatology

Other areas of specialty/work

Street address

Dermatology ward, Sina Hospital, Azadi Ave

City

Tabriz

Postal code

Phone

00

Fax

Email

esmailemamikhatab90@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hamide Azimi

Position

Dermatologist/Associate professor

Other areas of specialty/work

Street address

Dermatology ward, Sina Hospital, Azadi Ave.

City

Tabriz

Postal code

Phone

00

Fax

Email

hamide-azimi@yahoo.com

Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty