Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comprative Efficiacy of Tacrolimus 0.1% vs flucinolone onitment 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)

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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

Comprative Efficiacy of Tacrolimus 0.1% vs flucinolone onitment in patients with cutaneous lichen planus

Public title

Comprative Efficiacy of Tacrolimus 0.1% vs flucinolone onitment 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 ba applied 2 times daily to cover the entire lesion for 12 weeks.

Category
Treatment - Drugs

2

Description
In the second group flucinolone onitmen 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

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Person responsible for scientific inquiries

Contact

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Position
Dermatologist/Associate professor

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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