Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

comparison of efficacy of topical phenytoin versus topical flucinolon in treatment of cutaneous lichen planus

Protocol summary

Summary

1. Objective: With the purpose of finding a topical treatment with less adverse effect, we design a triple blinded RCT to compare topical corticosteroid as the conventional topical treatment of cutaneous lichen planus with topical phenytoin. 2.Design: Triple blinded randomized control trial without placebo 3. Setting and conduct: diagnosis of the disease was made clinically. 50 patients that were referred to Faghihi hospital was put in 2 groups of phenytoin cream and fluocinolone cream randomly. 4.participents including major eligibility criteria: both sex and all age group can enter the study. Exclusion criteria are pregnant and lactating women, other manifestation of lichen planus, or history of using topical and/or oral corticosteroid in last 1 month and sensitivity to phenytoin or fluocinolone 5. Intervention: patients apply their drug on the lesions twice daily. patients are visited in second, fourth and eighth weeks. 6. Main outcome measures: Patients are evaluated for color, scaling, thickness, and pruritus. all data are recorded by photography.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081231028N3**
Registration date: **2017-08-26, 1396/06/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-26, 1396/06/04

Registrant information

Name

Seyed Mohammad Salar Zaheryani

Name of organization / entity

Shiraz University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of efficacy of topical phenytoin versus topical flucinolon in treatment of cutaneous lichen planus

Public title

comparison of efficacy of topical phenytoin versus topical flucinolon in treatment of cutaneous lichen planus

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: patients with cutaneous lichen planus visiting at Faghihi Hospital in 2013 - 2018 exclusion criteria: pregnant and lactating woman; use of systemic or topical steroid in last 1 month; sensitivity reaction to phenytoin or fluocinolone; patient has oral, genital, actinic, pigmentosus type of lichen planus; concomitant

lichenplanopilaris.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple 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 Shiraz University of Medical Sciences

Street address
Shiraz University Of Medical Sciences , Zand Street , Shiraz , Iran

City
Shiraz

Postal code

Approval date
2014-07-26, 1393/05/04

Ethics committee reference number
CT_P_9354-5544

Health conditions studied

1

Description of health condition studied
cutaneous lichen planus

ICD-10 code
L43.8

ICD-10 code description
Other lichen planus

Primary outcomes

1

Description
color of lesions

Timepoint
before starting of treatment and 2,4 and 8 weeks after start of treatment

Method of measurement
Physical exam

2

Description
scale

Timepoint
before starting of treatment and 2,4 and 8 weeks after start of treatment

Method of measurement
Physical exam

3

Description
thickness of lesion

Timepoint
before starting of treatment and 2,4 and 8 weeks after start of treatment

Method of measurement
Physical exam

4

Description
pruritus

Timepoint
before starting of treatment and 2,4 and 8 weeks after start of treatment

Method of measurement
announcing the patient

Secondary outcomes

empty

Intervention groups

1

Description
use of flucinolone cream twice daily for 8 weeks

Category
Treatment - Drugs

2

Description
use of phenytoin cream twice daily for 8 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi Hospital of Shiraz
Full name of responsible person
Nahid Hemmatian Boroujeni
Street address
Dermatology Department,Shahid Faghihi Hospital, Zand street, Shiraz, Iran
City
SHIRAZ

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shiraz University of Medical Sciences
Full name of responsible person
Seyed Masoom Masoompour
Street address
Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran
City
Shiraz
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, Shiraz 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
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Person responsible for updating data

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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