

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### comparison of efficacy of topical phenytoin versus topical flucinolone 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 flucinolone cream randomly. 4. participants 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 flucinolone 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3234 1510

##### Email address

smszaheryany@sums.ac.ir

##### 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 flucinolone in treatment of cutaneous lichen planus

##### Public title

comparison of efficacy of topical phenytoin versus topical flucinolone 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 flucinolone; 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**

Shiraz University Of Medical Sciences

**Full name of responsible person**

Nahid Hemmatian Boroujeni

**Position**

Dermatology resident

**Other areas of specialty/work**

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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*