

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Evaluation of effect of oral zinc treatment in patients with oral lichen planus

#### Protocol summary

##### Summary

The aim of this study is to evaluate the effect of oral zinc on oral lichen planus lesions. Patients with oral lichen planus that referred to oral and maxillofacial medicine department of Shiraz dental school will be enrolled.

Those with special systemic disease or use of medications that influence on zinc uptake will be excluded from the study. In this study, 40 patients will be randomly assigned to the zinc capsules 250 mg and placebo (a capsule without active medication) for 8 weeks (twice a day), and healing based on type, extension and pain intensity will be evaluated 2 week, 2 month and 3 month after beginning of study. All patients use triamcinolone mouthwash 0.1 % for 3 week, simultaneously with oral zinc consumption.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015062213406N2**

Registration date: **2015-08-10, 1394/05/19**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-08-10, 1394/05/19

##### Registrant information

##### Name

Fahimeh Rezazadeh

##### Name of organization / entity

Dental school of Shiraz University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1628 9917

##### Email address

rezazadehf@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Science

##### Expected recruitment start date

2015-09-23, 1394/07/01

##### Expected recruitment end date

2016-03-10, 1394/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of effect of oral zinc treatment in patients with oral lichen planus

##### Public title

effect of zinc in oral lichen planus treatment

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: symptomatic oral lichen planus  
exclusion criteria: lichenoid reactions; immune deficiency ; consumption of medications that affect serum zinc level ; mal-absorption disorder ; The factor that changes the absorption of zinc (pregnancy , lactation, iron and calcium supplement) ; alcoholism ; drug therapy for lichen planus for 2 last month ; acute phase of post surgery ; malignancy; Patients who are not willing to participate in the study ; smoking ; sensitivity to zinc ; consumption of systemic steroids

##### Age

No age limit

##### Gender

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 40

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

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

empty

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

Shiraz University of Medical Science

**Street address**

Shiraz, Iran

**City**

Shiraz

**Postal code****Approval date**

2015-06-27, 1394/04/06

**Ethics committee reference number**

ir.sums.rec.1394.47

**Health conditions studied****1****Description of health condition studied**

lichen planus

**ICD-10 code**

L43.8

**ICD-10 code description**

Other lichen planus

**Primary outcomes****1****Description**

healing of oral lesion

**Timepoint**

2 week-2 month-3month

**Method of measurement**

size of lesion- oral extension- type of disease- pain level

**Secondary outcomes****1****Description**

recurrency

**Timepoint**

2 and 3 month

**Method of measurement**

recurrency period

**Intervention groups****1****Description**

zinc sulfate 250mg twice a day for 8 week

**Category**

Treatment - Drugs

**2****Description**

placebo zinc capsule without content twice a day 8 week

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shiraz Dental School

**Full name of responsible person**

Fahimeh Rezazadeh

**Street address**

Shiraz Dental School, Gom Abad, Shiraz, Iran

**City**

Shiraz

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Science

**Full name of responsible person**

Mahtab Memarpour

**Street address**

Iran, Shiraz, Shiraz University of Medical Science

**City**

Shiraz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shiraz University of Medical Science

**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 Dental School

**Full name of responsible person**

Fahimeh Rezazadeh

**Position**

Assistant professor of oral medicine

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Position**

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**Web page address****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*