Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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,extention 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
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Iran (Islamic Republic of)
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+98 71 1628 9917
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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
recurency
Timepoint
2 and 3 month
Method of measurement
recurency 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 Sciense
Full name of responsible person
Mahtab Memarpour
Street address
Iran, Shiraz, Shiraz University of Medical Sciense
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 Sciense

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
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Assistant professor of oral medicine
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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