

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of effectiveness of lycopene in improvement of erosive and atrophic oral lichen planus lesions

Protocol summary

Summary

Current randomized, double blind clinical trial is planned to evaluate effect of lycopene in treating erosive and atrophic forms of oral lichen planus lesions. 20 patients with oral lichen planus will be chosen out of all patients consulting zahedan dentistry collage their OLP lesions will be confirmed by histopathology. Age, medical history, sign and symptoms, duration, type, size and location of the lesions, in addition to any former history of skin lesions will be carefully written in informational forms. Diagnostic criteria is clinical and histopathological view of the lesions. Study subjects will be divided into 2 groups using quadruple blocks. In group A, patients with OLP will be examined and will receive topical corticosteroid in addition to lycopene patient will use the drug 4 times a day for 2 weeks (An hour before each meal and 20 minutes before sleep), and avoid eating, drinking and smoking for at least an hour after using the drug. One lycopene tab should be taken each day. In group B, patient will receive just topical corticosteroid. Both groups should be followed second week after starting the treatment. Follow up sessions will continue each week for 12 weeks. In each follow up session, size of the lesions will be measured by caliper.

General information

Acronym

OLP-oral lichen planus

IRCT registration information

IRCT registration number: **IRCT201601113133N8**

Registration date: **2016-04-18, 1395/01/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-04-18, 1395/01/30

Registrant information

Name

Fateme Arbabi Kalati

Name of organization / entity

Dental school of Zahedan

Country

Iran (Islamic Republic of)

Phone

+98 54 1244 1814

Email address

farbabi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Zahedan University of Medical Sciences

Expected recruitment start date

2015-12-11, 1394/09/20

Expected recruitment end date

2016-12-10, 1395/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effectiveness of lycopene in improvement of erosive and atrophic oral lichen planus lesions

Public title

The effect of lycopene in the treatment of oral lichen planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diagnostic criteria is clinical and histopathological view of the lesions. Exclusion criteria: patients with systemic disease, skin lichen planus, drug

user, pregnant women, smokers, patients with dysplastic lesions and lesions close to restorations and also patients receiving treatment for oral lesions was than a month ago.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 2

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Study subjects will be divided into 2 groups using quadruple blocks.

Secondary Ids

empty

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

Ethics committee of Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences-Dental school of Zahedan

City

Zahedan

Postal code**Approval date**

2015-06-27, 1394/04/06

Ethics committee reference number

IR.ZAUMS.7256

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

oral lichen planus

ICD-10 code

L43.8

ICD-10 code description

Other lichen planus

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

Reduction in size of the lesion

Timepoint

Before starting treatment, every week for 12 weeks after starting treatment

Method of measurement

In each follow up session size of the lesion will be measured by caliper.

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

Reduced pain of the lesion

Timepoint

Before starting treatment, every week for 12 weeks after starting treatment

Method of measurement

Use of Visual Analogue Scale (VAS) from 0- 10, 0: no pain sensation and 10: severe pain sensation

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

Intervention group: In this group, patients will receive topical corticosteroid in addition to lycopene, patient will use the drug 4 times a day for 2 weeks (An hour before each meal and 20 minutes before sleep), and avoid eating, drinking and smoking for at least an hour after using the drug. One lycopene tab should be taken each day.

Category

Treatment - Drugs

2**Description**

control group: In this group, patient will receive just topical corticosteroid and patient will use the drug 4 times a day for 2 weeks (An hour before each meal and 20 minutes before sleep), and avoid eating, drinking and smoking for at least an hour after using the drug.

Category

Placebo

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

Dental school of Zahedan

Full name of responsible person

Dr.Fateme Arbabi Kalati

Street address

Zahedan, eastern Azadagan street, dentistry college

City

zahedan

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

Vice chancellor for research,Zahedan University of Medical Sciences

Full name of responsible person

Dr.Fateme Arbabi Kalati

Street address

Dental school of Zahedan

City

zahedan

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,Zahedan 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**

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Fateme Arbabi Kalati

Position

associated professor

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Position

Associate Professor

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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