

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparing the therapeutic effects of curcumin mediated photodynamic therapy and topical corticosteroid in treatment of erosive OLP

Protocol summary

Study aim

The effect of curcumin mediated photodynamic therapy on healing of oral lichen planus

Design

A triple blind randomized controlled clinical trial, split mouth design. 7 patients with bilaterally erosive OLP enrolled and followed

Settings and conduct

This clinical trial will be conducted in 1401 in the Department of Oral and Maxillofacial Diseases of Shiraz Dental Faculty. 7. Patients with bilateral lesions of lichen planus are included in the study. There are 2 groups of lesions: lesions treated with triamcinolone mouthwash and placebo photodynamic therapy as control lesions, and lesions treated with triamcinolone mouthwash and curcumin-mediated photodynamic therapy. Each patient will receive placebo and photodynamic therapy in three sessions in one week. Patients are initially evaluated and followed up with follow-up sessions. Since all patients received triamcinolone acetonide for two weeks, the possible difference in results can be attributed to the therapeutic effect of curcumin-mediated photodynamic therapy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Symptomatic erosive lesions Exclusion criteria: Age < 18 years systemic diseases, lichenoid reactions

Intervention groups

14 sides with oral lichen planus are randomly divided into intervention and control sides by block randomization method. Since we do not intend to exclude any patient from standard OLP treatment, all groups will receive triamcinolone acetonide and nystatin mouthwash for two weeks, and will be tapered according to the standard protocol. Intervention lesions will receive three sessions of photodynamic therapy in one week, and control lesions will receive placebo gel and photodynamic therapy (placebo gel and off light source).

Main outcome variables

Thongprasom index, REU clinical score; VAS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221016056202N1**

Registration date: **2022-10-23, 1401/08/01**

Registration timing: **prospective**

Last update: **2022-10-23, 1401/08/01**

Update count: **0**

Registration date

2022-10-23, 1401/08/01

Registrant information

Name

hanieh farahmand

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 917 103 5288

Email address

h_farahmand@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-06, 1401/08/15

Expected recruitment end date

2023-02-04, 1401/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty		sequence was recorded until treatment allocation was completed for all 7 participants. Randomization will be done by the methodologist. Allocation concealment will be performed by the principal investigator. A sequence is written on each of the 14 cards and sealed. Pockets are placed in a box. An envelope will be assigned to each participant based on the order of registration.	
Scientific title	Comparing the therapeutic effects of curcumin mediated photodynamic therapy and topical corticosteroid in treatment of erosive OLP	Blinding (investigator's opinion)	Triple blinded
Public title	Comparing curcumin mediated photodynamic therapy and topical corticosteroid in treatment of oral OLP	Blinding description	The main researcher, who is responsible for examining and evaluating the lesions before and after the intervention, is unaware of which of the bilateral lesions of the patients is the case or the control. Another researcher is responsible for conducting the therapeutic intervention. The patients do not know which lesions are in the case or control group. The statistician who performs the data analysis is unaware of the case group and control. As a result, the study will be triple blind.
Purpose	Treatment	Placebo	Used
Inclusion/Exclusion criteria	Inclusion criteria: Clinical diagnosis of OLP by 2 oral medicine specialists Presence of bilateral erosive symptomatic lesions Patients willing to actively participate in the study Patients that are capable of performing the exact instructions of the treatment protocol. Exclusion criteria: Age < 18 years Pregnancy or lactation Uncontrolled systemic diseases (hepatopathies, coagulopathies, autoimmune or haematological diseases) History of allergic reactions to the active ingredient (curcumin) used in the clinical trial Presence of histological signs of dysplasia in the biopsy specimen Evidence of lichenoid lesions due to specific causes (dental materials, use of drugs inducing lichenoid reactions such as hypertensive or diabetic medications, etc.) Smokers or heavy drinkers of alcohol. Diabetic patients Patients with photosensitivity Lichenoid reaction	Assignment	Parallel
Age	From 18 years old	Other design features	
Gender	Both	Secondary Ids	empty
Phase	3	Ethics committees	
Groups that have been masked	- Participant - Investigator - Outcome assessor - Data analyser	1	
Sample size	Target sample size: 14 More than 1 sample in each individual Number of samples in each individual: 2 7 patient with bilateral symptomatic erosive lesions. a total of 14 lesions, 7 case lesions and 7 control lesions.	Ethics committee	
Randomization (investigator's opinion)	Randomized	Name of ethics committee	Research Ethics Committees of School of Dentistry-Shiraz University of Medical Sciences
Randomization description	Each patient with bilateral erosive OLP included in the study will be considered as follows: one side of the lesion will be the case and the other side will be the control lesion. . The experimental and control side of each patient is randomly selected using randomized blocks. Each block was considered with 4 allocations, including 2 allocations for the intervention and 2 allocations for the control group. Six possible sequences of treatment allocation are listed in each block, each written on a card. Each time a block was selected and the treatment	Street address	Zand Street, Namazi Square, Shiraz University of Medical Sciences
		City	shiraz
		Province	Fars
		Postal code	71956-15878
		Approval date	2022-08-31, 1401/06/09
		Ethics committee reference number	IR.SUMS.DENTAL.REC.1401.067
		Health conditions studied	
		1	
		Description of health condition studied	oral lichen planus
		ICD-10 code	L43
		ICD-10 code description	Lichen planus

Primary outcomes

1

Description

pain

Timepoint

days 0 and 7 and 14 and 28 and 56

Method of measurement

visual analogue scale

2

Description

size of lesion

Timepoint

days 0 and 7 and 14 and 28 and 56

Method of measurement

Digital caliper

3

Description

Clinical manifestations of inflammation

Timepoint

days 0 and 7 and 14 and 28 and 56

Method of measurement

Thongprasom sign scoring

4

Description

Clinical Efficacy of treatment

Timepoint

days 0 and 7 and 14 and 28 and 56

Method of measurement

REU

Secondary outcomes

1

Description

Allergy to curcumin

Timepoint

days 1 and 3 and 5

Method of measurement

Observe the side effects of increased sensitivity

Intervention groups

1

Description

Intervention group: In each photodynamic therapy session Sinanomin 1%(Topical gel contains %1 curcumin as nanoliposome from Exir Nanosina company will applied for 10 minutes in the side that is randomly selected as the case. After that a light cure device will be applied for irradiation with a blue light emitting wavelength of 470 nm for 5 min.

Category

Treatment - Drugs

2

Description

Control group: The other side of each patient that is considered as the control side with receive a placebo irradiation for 5 minutes with no light.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Shiraz University of Medical Sciences

Full name of responsible person

Hanieh Farahmand

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Shiraz, Qasrdasht St., corner of Mehr St., Shiraz
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hashem Hashempour

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Zand Street, in front of Palestine Street, Central
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Research Vice President of Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Hanieh Farahmand

Position

postgraduated student

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

I have decided to publish the article in domestic or foreign magazines. Complete information will be accessible in this way

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available