

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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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

Scientific title

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

Public title

Comparing curcumin mediated photodynamic therapy and topical corticosteroid in treatment of oral OLP

Purpose

Treatment

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, auto

immune 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

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

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.

Randomization (investigator's opinion)

Randomized

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

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.

Blinding (investigator's opinion)

Triple blinded

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.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Dentistry-

Shiraz University of Medical Sciences

Street address

Zand Street, Namazi Square, Shiraz University of

Medical Sciences

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Province

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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

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Full name of responsible person

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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