

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Clinical trial of the effect of curcumin on treatment of oral lichen planus

Protocol summary

Study aim

Determining the effect of curcumin on treatment of oral lichen planus in patients referring to Oral and Maxillofacial Diseases ward of Faculty of Dentistry, Tehran Islamic Azad University of Medical Sciences in 2019-2020

Design

Clinical trial with control group, parallel, not blinded and randomized

Settings and conduct

In this study the effect of curcumin on treatment of oral lichen planus in patients referring to Oral and Maxillofacial Diseases Faculty of Dentistry, Tehran Islamic Azad University of Medical Sciences, during 2019-2020 is evaluated. Blinding is not performed in this study.

Participants/Inclusion and exclusion criteria

The volunteers are selected from the patients with age 30-70 years. Patients are excluded from the study for case of corticosteroid therapy during two months prior to study, pregnancy or lactation, hypertension, diabetes and hemorrhagic disorders, medications that induce lichenoid reactions, dysplasia lesions, and skin lesions.

Intervention groups

The control group receives corticosteroid mouthwash (triamcinolone acetone 40mg in 1 ml with 19 cc distilled water, 5 cc each time) 3 times daily with antifungal mouthwash (20 drops of 100,000 IU oral suspension nystatin, 3 times/day) in addition to placebo capsules, once a day, after breakfast, for 4 weeks. In the intervention group, in addition to the standard treatment similar to the control group, curcumin capsules manufactured by Sina Co. with brand name of "Sina curcumin" containing 80 mg nanocrystalline curcumin are used once a day after breakfast for 4 weeks. In both groups, the patient uses the mouthwash for 2 minutes and then spits out and avoids eating and drinking for up to 30 minutes thereafter.

Main outcome variables

In this study, pain, irritation, lesion size and grading and

appearance of oral lichen planus lesions will be determined

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160420027501N2**

Registration date: **2019-11-23, 1398/09/02**

Registration timing: **prospective**

Last update: **2019-11-23, 1398/09/02**

Update count: **0**

Registration date

2019-11-23, 1398/09/02

Registrant information

Name

Mandana Khatibi

Name of organization / entity

Tehran Azad University faculty of Dentistry

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 4571

Email address

m_khatibi@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of curcumin on treatment of oral lichen planus

Public title

Effect of curcumin on oral lichen planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 30-70 years Diagnosis of oral lichen planus with biopsy

Exclusion criteria:

Corticosteroid therapy within two months before the study Pregnancy or lactation Hypertension, diabetes, hemorrhagic disorders Taking medications that cause lichenoid reactions Dysplasia lesions Skin lesions

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **28**

More than 1 sample in each individual

Number of samples in each individual: **14**

The minimum sample size required for each group is 13 samples

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned to two groups of intervention and control using block randomization with block sizes of 4. Randomization will be done using the software randomization option in Excel. The randomization process is performed by the study methodology consultant and clinical researchers are not aware of the randomization process. In order to be able to divide the samples into 4 blocks, the sample size of each group is 14 persons.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Medical Sciences, Tehran

Street address

Tehran Azad University faculty of Dentistry, 10th Neyestan St, Pasdaran Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2019-05-11, 1398/02/21

Ethics committee reference number

IR.IAU.DENTAL.REC.1398.006

Health conditions studied

1

Description of health condition studied

Oral Lichen Planus

ICD-10 code

L43

ICD-10 code description

Lichen plaus

Primary outcomes

1

Description

Pain and Soreness

Timepoint

Before treatment and 2 , 4 weeks after treatment

Method of measurement

Asking from patients, based on visual analogue scale (VAS) and between 0-10

2

Description

size of the lesion

Timepoint

Before treatment and 2 , 4 weeks after treatment

Method of measurement

by the Michigan 'O' Probe in mm

3

Description

Scoring and appearance of oral lichen planus lesions

Timepoint

Before treatment and 2 , 4 weeks after treatment

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Receives corticosteroid mouthwash (triamcinolone acetone 40mg in 1 ml with 19 cc distilled water, 5 cc each time) 3 times daily with antifungal mouthwash (20 drops of 100,000 IU oral suspension nystatin, 3 times/day) in addition to placebo capsules, once a day, after breakfast, for 4 weeks.

Category

Placebo

2

Description

Intervention group: In the intervention group, in addition to the standard treatment similar to the control group, curcumin capsules manufactured by Sina Co. with brand name of "Sina curcumin" containing 80 mg nanocrystalline curcumin are used once a day after breakfast for 4 weeks. In both groups, the patient uses the mouthwash for 2 minutes and then spits out and avoids eating and drinking for up to 30 minutes thereafter.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Azad University Faculty of Dentistry, Oral Medicine Department

Full name of responsible person

Dr mandana Khatibi

Street address

Tehran Azad University faculty of Dentistry, 10th Neyestan St, Pasdaran Ave, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mandana Khatibi

Street address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Nazanin Ghobadi

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Mandana Khatibi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Resident

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

IPD collected for the primary outcome measure only

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

Everybody

Under which criteria data/document could be used

Everybody

From where data/document is obtainable

Call Dr. Mandana Khatibi

What processes are involved for a request to access data/document

Send an email to m_khatibi@dentaliau.ac.ir and wait for response

Comments