Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 forin 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)

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+98 21 2256 4571

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mandana Khatibi
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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

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Full name of responsible person
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Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

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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