

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Effect of oral curcumin on the size, pain and burning sensation of oral lichen planus lesions

#### Protocol summary

2016-10-29, 1395/08/08

#### Summary

The aim of this study was to determine the effect of 80 mg oral curcumin capsule, made by Eksir Nano Sina Company, on treatment of oral lichen planus of patients referred to center of oral and maxillofacial disease of guilan dentistry faculty. this study is accomplished, single blind, uni center, without any randomization and in 3th phase of clinical trial.13 patients with oral lichen planus without any systemic disease will be enrolled in this study. Patients didn't use local corticosteroid from 2 weeks ago and systemic corticosteroid from 1 last month they take a drug and then use oral curcumin for 1 month, once a day after breakfast. Pain, burning sensation and size of the lesions assess before taking drug, and at the end of 1,2,4,8 weeks after treatment. Inclusion criteria are patients with oral lichen planus, who are volunteer and confirmed by histopathological evaluation. exclusion criteria is pregnant women, breast feeding women, patients who take corticosteroid, patients with peptic ulcer, gall-bladder stone, increased hepatic enzyme, and patients who take anti coagulation drugs, like warfarin. Treatment intervention is Consumption 80 mg oral curcumin capsule once a day for 1month. Primary outcome measure is pain and burning sensation of lesions, and secondary outcome measure is size of the lichen planus lesions.

#### Registrant information

##### Name

Sayed Javad Kia

##### Name of organization / entity

Guilan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1323 0775

##### Email address

djavadkia@gums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

research vice chancellorship of guilan univesity of medical science

#### Expected recruitment start date

2016-07-10, 1395/04/20

#### Expected recruitment end date

2016-09-10, 1395/06/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of oral curcumin on the size, pain and burning sensation of oral lichen planus lesions

#### Public title

Effect of oral curcumin on the size, pain and burning sensation of oral lichen planus lesions

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: patients with oral lichen

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201607032950N4**

Registration date: **2016-10-29, 1395/08/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

planus(confirmed by clinical examination, biopsy and histopathological evaluation) exclusion criteria: pregnant woman, breast feeding woman, patients who take corticosteroid, patients with peptic ulcer, gall-bladder stone, increased hepatic enzyme, and patients who take anti coagulation drug, like warfarin.

#### Age

From **20 years** old to **70 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **13**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Single

#### Other design features

single blind

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ethics committee of guilan university of medical science

##### Street address

opposite of sepah bank, western shahid beheshti blv, rasht

##### City

rasht

##### Postal code

#### Approval date

2016-06-14, 1395/03/25

#### Ethics committee reference number

IR.GUMS.REC.1395.90

## 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 and burning sensation

#### Timepoint

before using drug and 1,2,4,8 after using drug

#### Method of measurement

use of visual analogue scale(VAS)

## Secondary outcomes

### 1

#### Description

Size of the lichen planus lesions

#### Timepoint

Before treatment and 1,2,4,8 week after treatment

#### Method of measurement

tongprasom scale(0-5)

## Intervention groups

### 1

#### Description

Consumption 80 mg oral curcumin capsule once a day for 1 month

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

dental school, guilan university of medical science

##### Full name of responsible person

Dr Seyad Javad Kia

##### Street address

pardis, imam str, rasht

##### City

rasht

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

vice chancellor for research, guilan university of medical science

##### Full name of responsible person

Dr Rasool Tabari

##### Street address

opposite of sepah bank, western shahid beheshti blv, rasht

**City**  
rasht

**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, guilan university of medical science

**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**  
Dental school of guilan university of medical science

**Full name of responsible person**  
Dr Seyed Javad Kia

**Position**  
Assistant professor

**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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*