

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

A comparison of the effect of oral Curcumin and Prednizolon on pain relief and size of the lesions in patients with Oral Lichen Planus lesions who refer to OMF center of Dental University of Gilan and private office in Rasht 1396-97

Protocol summary

Study aim

The purpose of this study is to compare of the effect of 80 mg oral Curcumin capsule, made by Eksir Nano Sina Company and 10mg Prednizolon, on pain & size of lesions of Oral lichen planus.

Design

Phase 3 clinical trial having 2 groups of 28 members, double blinded and randomized with block identifier, block size, sequence within block, treatment, code.

Settings and conduct

56 Patients in divides into 2 groups of 28,that one of them will recieve nano corcumin cap or 10mg prednizolon for 1 month. examination and evaluation in initial of study then in 1,2,4 week intervals will be record. Information of randomizing will just give to the secretary & drugs will be count and put into an envelope for each person. information for correct use of drugs will be give to patients separately in another room.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with Oral lichen planus clinically and histologically. Exclusion criteria: pregnancy,breastfeeding,patients who take Corticosteroid,patients with increased hepatic enzyme and patients who take anti coagulation and anti platelet drug, like Warfarin.orthodontic appliances,patients with peptic ulcer, gall-bladder stone.existance of neoplasms or viral infections.receiving topical treatment for OLP during last 2 weeks or systemic treatment of OLP during last 4 weeks.consumption of Azathioprine, Cyclosporine, UVA,PUVA or UVB during last month.the presence of allergies to Corticosteroids or herbal drugs like Curcumin.

Intervention groups

Group 1: Consumption of 80mg Curcumin capsules in nano form once a day after breakfast for 1 month Group 2: Consumption of two 5mg Prednizolon tablet after breakfast for 1 month, and for tapering 5mg daily

Prednizolone for 10 days.

Main outcome variables

Pain levels will be evaluate with VAS scale. Size of lesions will be evaluate with Thongprasom scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100101002950N5**

Registration date: **2019-02-09, 1397/11/20**

Registration timing: **prospective**

Last update: **2019-02-09, 1397/11/20**

Update count: **0**

Registration date

2019-02-09, 1397/11/20

Registrant information

Name

Sayed Javad Kia

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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djavadkia@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-19, 1397/11/30

Expected recruitment end date

2019-05-21, 1398/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effect of oral Curcumin and Prednizolon on pain relief and size of the lesions in patients with Oral Lichen Planus lesions who refer to OMF center of Dental University of Gilan and private office in Rasht 1396-97

Public title

A comparison of the effect of oral Curcumin and Prednizolon on pain relief and size of the lesions in patients with Oral Lichen Planus lesions who refer to OMF center of Dental University of Gilan and private office in Rasht 1396-97

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with Oral lichen planus(confirmed by clinical examination, biopsy and histopathological evaluation)

Exclusion criteria:

Pregnancy Breastfeeding Patients who take corticosteroid Patients with increased hepatic enzyme and patients who take anti coagulation and anti platelet drug, like Warfarin. Orthodontic appliances Patients with Peptic ulcer, Gall-bladder stone Existance of any neoplasms or viral infections Receiving topical treatment for OLP during last 2 weeks or systemic treatment of OLP during last 4 weeks Consumption of Azathioprine, Cyclosporine, UVA,PUVA or UVB during last month The presence of allergies to Corticosteroids or herbal drugs like Curcumin

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 56

Randomization (investigator's opinion)

Randomized

Randomization description

For divition of participants into 2 random groups of 28 members, first give each participant number 1 to 56. then we will devide them randomly(complete

randomization excel file is available) : block identifier, block size, sequence within block, treatment, code • 1, 4, 1, Group B, OK1 • 1, 4, 2, Group A, NY0 • 1, 4, 3, Group A, CA8 • 1, 4, 4, Group B, UP6 • 2, 4, 1, Group B, LA0 • 2, 4, 2, Group A, VK2 • 2, 4, 3, Group B, AY0 • 2, 4, 4, Group A, LW6 • 3, 4, 1, Group A, CM7 • 3, 4, 2, Group B, BX0

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be double-blinde. the information of randomization just will be give to the secretary and drugs for 2 groups will be count and put into an envelope for each person. information for correct use of drugs will be give to patients separately in another room.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Guilan University of Medical Sciences

Street address

Opposite of Sepah bank, Western Shahid Beheshti Blv

City

Rasht

Province

Guilan

Postal code

41941-73774

Approval date

2018-11-02, 1397/08/11

Ethics committee reference number

IR.Gums.Rec.1397.295

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**

Severity of pain

Timepoint

Before treatment and 1,2,4 week after treatment

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 week after treatment

Method of measurement

Tongprasom scale(0-5)

Intervention groups

1

Description

Intervention group: Consumption of 80 mg oral Curcumin capsule once a day for 1 month

Category

Treatment - Drugs

2

Description

Control group: Consumption of 2 capsules of Prednisolone 5mg once a day for 1 month and after that for 10 days 5mg Prednisolone per day for tapering

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental school, Guilan University of Medical Sciences

Full name of responsible person

Dr Seyad Javad Kia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

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?

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Dr Seyed Javad Kia

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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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

data are shareable after making them unidentifiable.

When the data will become available and for how long

accessibility starts from 6 month after publish

To whom data/document is available

data will be accessible for researchers of universal and scientific institution.

Under which criteria data/document could be used

they can use them with reference

From where data/document is obtainable

dr seyed javad kia djavadkia@yahoo.com

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

after receiving the request, data will be send to applier during 1 month

Comments