Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Oct 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 prednizolone 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 secretory & 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 clinicaly 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 appliences.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 Prednizolone 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

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Iran (Islamic Republic of)

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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 appliences 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 division 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 secretory 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 Prednizolone 5mg once a day for 1 month and after that for 10 days 5mg Prednizolone 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

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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?

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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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