

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Evaluation of the efficacy of oral curcumin on recurrency and number of complex aphthous lesions in the patients referred to the Oral and maxillofacial medicine Department of Guilan Dental School in 2021-2022

Protocol summary

Study aim

Determining the effect of oral curcumin on recurrence and number of complex aphthous lesions

Design

Phase 2-3 clinical trial in 15 patients with complex aphthous ulcer will be treated with Sinacurcumin and Triadent ointment for 1 month and will be followed for another month

Settings and conduct

15 patients with complex aphthous will be referred to the Dental school of Guilan university. They will be treated for 1 month with 40mg Sinacurcumin twice a day and 0.1% Triadent ointment as a topical application. The patient will be examined in the first visit and in weeks 2, 4 and 8

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients between the ages of 20 and 60 years with complex aphthous ulcers; developed in less than 72 hours. Exclusion criteria: Patients taking topical medication to treat the aphthous in the last 2 weeks or taking systemic medication in the last 1 month, Patients with systemic diseases such as intestinal and gastric diseases (Crohn's and ulcerative colitis), Behcet's disease, Reiter's syndrome and gallstones, Patients with anxiety disorders, Patients with brackets, Pregnant and lactating women, Patients with a history of alcohol and drug use, Patients treated with immunosuppressants, chemotherapy, and immunomodulatory drugs over the past year, History of allergies to plant compounds including turmeric, High liver enzymes, Use of anticoagulants or antiplatelets (curcumin has an inhibitory effect on platelet aggregation) such as Warfarin, Aspirin, Clopidogrel, Enoxaban, Rivaroxaban, Heparin, and Enoxaparin, History of gastric ulcer and duodenal ulcer, Patients with inadequate literacy who do not understand the consent form.

Intervention groups

Intervention group: Sinacurcumin capsule.

Main outcome variables

Recurrence of complex aphthous lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100101002950N7**

Registration date: **2021-09-17, 1400/06/26**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-17, 1400/06/26**

Update count: **0**

Registration date

2021-09-17, 1400/06/26

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

Expected recruitment start date

2021-09-16, 1400/06/25

Expected recruitment end date

2021-11-16, 1400/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of oral curcumin on recurrency and number of complex aphthous lesions in the patients referred to the Oral and maxillofacial medicine Department of Guilan Dental School in 2021-2022

Public title

Evaluation of the efficacy of oral curcumin on complex aphthous

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients between the ages of 20 and 60 years Complex aphthous ulcers, which include: a number of painful aphthous lesions on the oral mucosa that appear intermittently and heal slowly; Created in less than 72 hours

Exclusion criteria:

Patients taking topical medication to treat the aphthous in the last two weeks or taking systemic medication in the last one month Patients with systemic diseases such as intestinal and gastric diseases (Crohn's and ulcerative colitis), Behcet's disease, Reiter's syndrome and gallstones Patients with anxiety disorders Patients with brackets Pregnant and lactating women Patients with a history of alcohol and drug use Patients treated with immunosuppressants, chemotherapy, and immunomodulatory drugs over the past year History of allergies to plant compounds, including turmeric High liver enzymes Use of anticoagulants or antiplatelets (curcumin has an inhibitory effect on platelet aggregation) such as Warfarin, Aspirin, Clopidogrel, Enoxaban, Rivaroxaban, Heparin and Enoxaparin History of gastric ulcer and duodenal ulcer Patients with inadequate literacy who do not understand the consent form

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of Guilan University of Medical Science

Street address

Assistance office of Research and Technology, Namjoo St. Shahid Siadati St., in front of 17 Shahrivar hospital,

City

Rasht

Province

Guilan

Postal code

41941-73774

Approval date

2021-09-01, 1400/06/10

Ethics committee reference number

IR.GUMS.REC.1400.257

Health conditions studied**1****Description of health condition studied**

Oral complex aphthous

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes**1****Description**

The recurrence of ulcers

Timepoint

2, 4 and 8 weeks after consumption of the medicine

Method of measurement

With physical examination of patients and based on the time after taking the drug that the disease will occurs again

2**Description**

The number of aphthous lesion

Timepoint

At the beginning of treatment and 2 weeks, 4 weeks and 8 weeks after consumption of the medicine

Method of measurement

Count the number of lesions through examination

3

Description

Functional complications

Timepoint

At the beginning of treatment and 2 weeks, 4 weeks and 8 weeks after consumption of the medicine

Method of measurement

Use of visual analogue scale (VAS) from 0-10. 0: The least discomfort and interference of the lesions with the patient speaking, chewing and brushing. 10: The highest amount of interference

4

Description

Patient satisfaction with treatment

Timepoint

2, 4 and 8 weeks after consumption of the medicine

Method of measurement

Use of visual analogue scale. 0-7: Dissatisfaction 8-10: Satisfaction

Secondary outcomes

1

Description

The size of aphthous lesion

Timepoint

At the beginning of treatment and 2 weeks, 4 weeks and 8 weeks after consumption of the medicine

Method of measurement

Using a sterile vernier caliper

2

Description

The severity of pain

Timepoint

At the beginning of treatment and 2 weeks, 4 weeks and 8 weeks after consumption of the medicine

Method of measurement

Use of visual analogue scale (VAS) from 0-10. 0: no pain - 10: severe pain

Intervention groups

1

Description

Intervention group: Consumption of 2 oral siva Curcumin capsule 40 mg once a day for 1 month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Oral and Maxillofacial Diseases, Guilan Dental School

Full name of responsible person

Dr. Seyed Javad Kia

Street address

Guilan dental school, Fuman-Saravan Rd

City

Rasht

Province

Guilan

Postal code

41941-73774

Phone

+98 13 3348 6416

Fax

+98 13 3348 6423

Email

DJavadkia@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Naghipoor

Street address

Assistance office of Research and Technology, in front of 17 Shahrivar hospital, Shahid Siadati St., Namjoo St.

City

Rasht

Province

Guilan

Postal code

41941-73774

Phone

+98 13 3333 6394

Fax

+98 13 3333 6395

Email

research@gums.ac.ir

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

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Guilan dental school, Fuman-Saravan Rd

City

Rasht

Province

Guilan

Postal code

41941-73774

Phone

009813336416

Fax

+98 13 3348 6423

Email

Djavadkia@gums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Dr. Seyed Javad Kia

Position

Associated professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Dr. Seyed Javad Kia

Position

Associated professor

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41941-73774

Phone

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Fax

+98 13 3348 6423

Email

Djavadkia@gums.ac.ir

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 will shareable after making them unidentifiable

When the data will become available and for how long

Accessibility will starts from 6 month after publish

To whom data/document is available

Data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

They can use them with refrence

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, the documents will be delivered to the applicant within one month.

Comments