Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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 1month 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 20and60years with complex aphthous ulcers; developed in less than 72 hours. Exclusion criteria: Patients taking topical medication to treat the aphthous in the last 2weeks or taking systemic medication in the last 1month, 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, Epixaban, 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)

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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 bracets 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, Epixaban, 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 8weeks 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 analoge 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 8weeks after consumption of the medicine
Method of measurement
Use of visual analoge 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 analoge scale (VAS) from 0-10. 0:no pain - 10: severe pain

Intervention groups

1

Description
Intervention group:Consumption of 2 oral sina 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
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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.
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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

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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 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