

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of effectiveness of the bioadhesive pastes curcumin and topical corticosteroid for the treatment of Aphthous Stomatitis

Protocol summary

Study aim

Comparison of effectiveness of the bioadhesive pastes curcumin and topical corticosteroid for the treatment of Aphthous Stomatitis

Design

Clinical trials with parallel , double -blind, randomized groups

Settings and conduct

This study will be performed on all patients referred to the the School of Dentistry of Zahedan University in 2021, whose diagnosis of minor oral aphthous in their oral mucosa has been confirmed. Sampling will be done based on inclusion and exclusion criteria and for each treatment group, 30 samples and a total of 60 samples will be considered.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: Patients with RAS with duration of 1 day of beginning of their symptoms
Exit criteria: 1. Use of systemic Aphthous treatment (over the past three months) and topical treatment during the procedure 2. Atypical Aphthous cases and cases suspected of Behcet's syndrome, inflammatory bowel disease, and ... 3. Pregnant or lactating women 4. Patient with Diabetes 5. High blood pressure 6. Duration of the Aphthous more than one day 7. The patients who did not sign the letter of informed consent

Intervention groups

first group administration of Curcumin; second group administration of Adcotryl on oral aphthous lesions and evaluation of the severity of pain, size of the wound and the recovery time before and after administration.

Main outcome variables

Evaluation of pain and burning symptoms and size of ulcer present in patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141220020377N5**

Registration date: **2021-10-02, 1400/07/10**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-02, 1400/07/10**

Update count: **0**

Registration date

2021-10-02, 1400/07/10

Registrant information

Name

Tahereh Nosratzahi

Name of organization / entity

Dental School of Zahedan University

Country

Iran (Islamic Republic of)

Phone

+98 915 348 0151

Email address

nosratzahi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-09, 1400/06/18

Expected recruitment end date

2022-06-12, 1401/03/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of the bioadhesive pastes curcumin and topical corticosteroid for the treatment of Aphthous Stomatitis

Public title

Comparison of effectiveness of the bioadhesive pastes curcumin and topical corticosteroid for the treatment of Aphthous Stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with RAS symptoms for less than 1 day

Exclusion criteria:

The patients who did not sign the letter of informed consent Patient with hypertension (greater than 80/130) cases suspected of Behcet's syndrome, inflammatory bowel disease. Pregnant or lactating women Patients with Diabetes Patients Use of systemic aphthous treatment (over the past three months) and topical treatment during the procedure Atypical aphthous cases Patients with RAS symptoms for more than 1 day

Age

From **12 years** old to **79 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are selected by available and non-probabilistic methods and from among them, patients who meet the inclusion criteria will be selected. Then patients will be divided into two groups of control and intervention by simple random method (code is assigned to each sample) and using SPSS statistical software.

Blinding (investigator's opinion)

Double blinded

Blinding description

How to use each drug was typed in a container containing an anonymous drug, in an opaque envelope. Each envelope was given to the patient at random. The name of the drug was specified as A and B and was written in the questionnaire on which the test results of the patients were recorded by the researcher. So that it can be analyzed only by the statistics consultant at the end of the research.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Research Vice Chacellorship of Zahedan University of Medical Sciences

Street address

Oral medicine department, faculty of dentistry, Azadegan street,Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816745534

Approval date

2020-06-30, 1399/04/10

Ethics committee reference number

IR.ZAUMS.REC.1399.489

Health conditions studied

1

Description of health condition studied

Recurrent oral aphthae

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes

1

Description

pain sensation

Timepoint

before starting study,days 1,4 ,7 ,10

Method of measurement

Use of visual analoge scale (VAS) from 0- 10, 0: no pain

Secondary outcomes

1

Description

Recurrent aphthous ulcers

Timepoint

days 1,4,7,10

Method of measurement

Measuring of ulcers by ruler

Intervention groups

1

Description

Control: Triamcinolone in oral base Ointment (Triadent),

topical use in oral mucosa ulcer, 3 time/day, after meal, for 10 days

Category

Treatment - Drugs

2

Description

Intervention: Curcumin Gel-topical use in oral mucosa ulcer, 3 time/day, after meal for 10 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan University Of Medical Sciences

Full name of responsible person

Tahereh Nosratzahi

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Oral medicine department, faculty of dentistry, Azadegan street,Zahedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Noor mohammadBakhshani

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Grant name

Research Vice Chacellorship of Zahedan University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Tahereh Nosratzahi

Position

Associated Professor , Department of Oral Medicine, Dental Research Center, Zahedan University Of Me

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

No- There is no plan to make this available at the present time

When the data will become available and for how long

starting 10 months after publication

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

It is permitted to use the data in other studies with reference.

From where data/document is obtainable

Nosratzahi@zaums.ac.ir

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

Sending email to authors

Comments