

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Evaluation of the effect of Punica granatum flower tablet on pain and healing of minor recurrent aphthous stomatitis: a randomized clinical trial

Protocol summary

Study aim

This study aims to evaluate the effect of Punica granatum flower tablets on the size and pain of patients with recurrent aphthous stomatitis.

Design

The total sample size is 24 patients. 12 participants in the evaluation group and 12 participants in the control group will be enrolled. Patients with recurrent aphthous stomatitis will be divided randomly (block randomization) into 2 experimental and control groups. In experimental and control groups patients will receive pomegranate flower tablets and oral paste Triadent 0.1% respectively, three times a day for 7 days.

Settings and conduct

This study is not blinded. The patients who will be referred to Shiraz Dental School for their recurrent aphthous stomatitis will be enrolled.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The participants should have recurrent aphthous stomatitis, The participants should not use other routine medication for RAS during evaluation, less than 24 hours from lesion onset time, The participants should not use systemic or topical corticosteroid since 1 month ago. Exclusion criteria: The patients with Behcet disease, Crohn's disease, Reiter's syndrome, or any other inflammatory disease, pregnant women.

Intervention groups

In this study, the effect of Punica granatum flower tablets on the size and pain of patients with recurrent aphthous stomatitis will be assessed. In the control group, triadent oral paste will be prescribed for recurrent aphthous stomatitis treatment.

Main outcome variables

The amount of pain, the size of lesion, healing period

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120101008585N12**

Registration date: **2022-01-26, 1400/11/06**

Registration timing: **prospective**

Last update: **2022-01-26, 1400/11/06**

Update count: **0**

Registration date

2022-01-26, 1400/11/06

Registrant information

Name

Fatemeh Lavaee

Name of organization / entity

Shiraz Dental School

Country

Iran (Islamic Republic of)

Phone

+98 71 1631 9309

Email address

lavaeef@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-21, 1401/02/31

Expected recruitment end date

2022-10-22, 1401/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Punica granatum flower tablet on pain and healing of minor recurrent aphthous stomatitis: a randomized clinical trial

Public title

The effect of Punica granatum flower tablet on recurrent aphthous stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having recurrent aphthous stomatitis The participants should not use other routine medication for RAS during the evaluation Less than 24 hours from lesion onset time The participants should not use systemic or topical corticosteroid since 1 month ago.

Exclusion criteria:

The participants with other diseases including Behcet disease, Crohn disease, Reiter's syndrome, or any other inflammatory disease The participants who have used analgesic mouthwash or systemic analgesia since 3 days ago pregnant women

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Each block with 4 allocations, consisting of 2 allocations for intervention and 2 for the control group were considered. Six possible sequences of treatment allocation in each block were listed and each one was written on a card. Each time a block had been selected and the sequence of treatments was registered until the treatment allocations become completed for all 24 patients (6 blocks).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Ghasrdasht

City

Shiraz

Province

Fars

Postal code

7195845379

Approval date

2020-07-26, 1399/05/05

Ethics committee reference number

IR.SUMS.DENTAL.REC.1399.136

Health conditions studied

1

Description of health condition studied

Recurrent aphthous stomatitis

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes

1

Description

The amount of pain

Timepoint

Day1,2,3,4,5,6,7 before and after treatment

Method of measurement

Visual analogue scale

2

Description

The size of lesion

Timepoint

Day1,2,3,4,5,6,7

Method of measurement

Degreed tongue blade

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with recurrent aphthous stomatitis in the experimental group will receive pomegranate flower tablets 3 tablets daily for 7days.

Category

Treatment - Drugs

2**Description**

Control group: In the control group oral paste Triadent0.1% (Raha pharma. Isfahan-Iran) will be prescribed three times a day for 7 days

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Shiraz Dental School

Full name of responsible person

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Rezaianzade

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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

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Fateme Lavaee

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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

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Full name of responsible person

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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

Statistical analysis file

When the data will become available and for how long

The data will be given to the requester by email.

To whom data/document is available

The data will be given to the requester by email.

Under which criteria data/document could be used

The data will be given to the requester by email.

From where data/document is obtainable

The data will be given to the requester by email.

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

The data will be given to the requester by email.

Comments