Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 7days.

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 used 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 aphtus stomatis 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 anloge 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 centers

1

Recruitment center
Name of recruitment center
Shiraz Dental School
Full name of responsible person
Fatemeh Lavaee
Street address
Ghasrdasht
City
Shiraz
Province
Fars
Postal code
7195845379
Phone
+98 71 3626 3193
Email
lavaeef@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr.Rezaianzade
Street address
Ghasrdasht
City
Shiraz
Province
Fars
Postal code
7195845379
Phone
+98 71 3212 2438
Email
lavaeef@sums.ac.ir
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
Fatemeh Lavaee
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Ghasrdasht
City
Shiraz
Province
Fars
Postal code
7195845379
Phone
+98 71 3626 3193
Email
lavaeef@sums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Fatemeh Lavaee
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Ghardasht
City
Shiraz
Province
Fars
Postal code
7195845379
Phone
+98 71 3626 3193

Email
lavaeef@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Fatemeh Lavaee
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Ghasrdasht
City
Shiraz
Province
Fars
Postal code
7195845379
Phone
+98 71 3626 3193
Email
lavaeef@sums.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
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