

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Jujube-chicory-honey mouthwash effect on pain control and size of aphthous lesions in patients with recurrent aphthous stomatitis in comparison with Triadent .

Protocol summary

Study aim

Evaluation of the effect of jujube-chicory-honey mouthwash on pain and healing of recurrent aphthous stomatitis

Design

This study is a clinical trial in phase 2 with control group. It is designed as a parallel, double blinded and randomized evaluation. 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 jujube-chicory-honey mouthwash and oral paste Triadent 0.1% respectively, three times a day for 7 days.

Settings and conduct

The patients who will be referred to Oral and Maxillofacial Diseases Department of Shiraz Dental School with recurrent aphthous stomatitis will be enrolled. This study is double blinded. The outcome assessor and statistical analyzer will not know the type of prescribed treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having recurrent aphthous stomatitis, not using other routine medication for RAS during evaluation, less than 24 hours from lesion onset time, not using 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

Intervention group: Patients with recurrent aphthous stomatitis in the experimental group will receive jujube-chicory-honey mouthwash 3 times daily for 7 days. Control group: In the control group oral paste Triadent 0.1% (Raha pharma. Isfahan-Iran) will be

prescribed three times a day for 7 days

Main outcome variables

Pain, the size of lesion, healing period

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120101008585N15**

Registration date: **2022-04-03, 1401/01/14**

Registration timing: **prospective**

Last update: **2022-04-03, 1401/01/14**

Update count: **0**

Registration date

2022-04-03, 1401/01/14

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

2022-04-09, 1401/01/20

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Jujube-chicory-honey mouthwash effect on pain control and size of aphthous lesions in patients with recurrent aphthous stomatitis in comparison with Triadent .

Public title
Jujube-chicory-honey mouthwash effect on pain and size of recurrent aphthous stomatitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Having recurrent aphtus stomatis (RAS) Not using other routine medication for RAS during the evaluation Less than 24 hours from lesion onset time Not using 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
From **18 years** old

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 will be considered. Six possible sequences of treatment allocation in each block will be listed. 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

2020-09-06, 1399/06/16

Ethics committee reference number

IR.SUMS.DENTAL.REC.1399.187

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

Pain

Timepoint

Days 1, 2, 3, 4, 5, 6, 7 before and after treatment

Method of measurement

Visual anloge scale

2

Description

The size of lesion

Timepoint

Days 1, 2, 3, 4, 5, 6, 7 before and after treatment

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 jujube-chicory-honey mouthwash on recurrent aphthous stomatitis 3 times daily for 7 days.

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, Mehr Ave., Shiraz Dental school

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 Abbas Rezaianzade

Street address

Ghasrdasht, Mehr Ave., Shiraz Dental school

City

Shiraz

Province

Fars

Postal code

7195845379

Phone

+98 71 3212 2438

Fax**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

Ghasrdasht

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
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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 data file

When the data will become available and for how long

The data will be given to the requester by email up to 1 year after results registration.

To whom data/document is available

The data will be given to the requester by email up to 1 year after results registration.

Under which criteria data/document could be used

The data will be given to the requester by email up to 1 year after results registration.

From where data/document is obtainable

The data will be given to the academic requester by email up to 1 year after results registration.

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

The data will be given to the academic requester by email up to 1 year after results registration.
lavaeef@sums.ac.ir

Comments