

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 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**

Ghasrasht

**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 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