

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation the effect of Rhus Coriaria on pain and size of oral recurrent aphtus stomatitis in patients reffered to Shiraz Dental School

#### Protocol summary

##### Study aim

The aim of this study is evaluating the effect of somaq on size and pain of patients with recurrent aphtus stomatitis.

##### Design

22 patients with active RAS will be divided randomly (block randomization) to 2 experimental and control group.

##### Settings and conduct

This randomized phase 2 clinical trial will be done in 2017 on the patients who will be referred to Shiraz Dental School for their RAS. In experimental group 11 patients will receive somaq pills but in the control group oral paste triadent0.1 three times in a day will be used by 11participants. In the experimental group the patients will use 3pills daily for 7days.The researcher will evaluate VAS (visual analogue scale) of participants before and after using pills (on day 0,1,2,3,4,5,6,7). The size of a specific ulcer in each patient also will be measured by graded tongue blade on day 0,1,2,3,4,5,6,7. The healing process will be evaluated by measuring oral ulcer size and patient pain will be studied by VAS.

##### Participants/Inclusion and exclusion criteria

The patient with RAS since less than 72h will be enrolled in this research. They should have not use any topical or oral corticosteroid since a month before. Also they should not use any analgesic mouthwash or systemic analgesic since 3 days before this evaluation. The participant who will sign the written consent form will be recruited.

##### Intervention groups

In experimental group 11 patients will receive somaq pills but in the control group oral paste triadent 0.1 three times in a day will be used by 11participants. In the experimental group the patients will use 3 pills daily for 7days.

##### Main outcome variables

level of pain; size of lesion

#### General information

##### Reason for update

##### Acronym

recurrent aphtus stomatitis (RAS)

##### IRCT registration information

IRCT registration number: **IRCT20120101008585N4**

Registration date: **2017-12-24, 1396/10/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2017-12-24, 1396/10/03**

Update count: **0**

##### Registration date

2017-12-24, 1396/10/03

##### 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

2017-06-22, 1396/04/01

##### Expected recruitment end date

2018-03-20, 1396/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Evaluation the effect of Rhus Coriaria on pain and size of oral recurrent aphtus stomatitis in patients referred to Shiraz Dental School

**Public title**

Evaluation the effect of Rhus Coriaria on oral aphtus stomatitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having recurrent aphtus stomatis not using other routine prescribed medication for RAS during evaluation less than 72 hour from emerging of the lesion not using systemic or topical corticosteroid since 1 month ago Patient more than 6 years old

**Exclusion criteria:**

patients with other diseases related to behcet , crohn disease, rheiter syndrome or any other inflammatory disease using analgesic mouthwash or systemic analgesia since 3 days ago pregnant women

**Age**

From 6 years old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

No information

**Sample size**

Target sample size: 22

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

simple randomization Unit of randomization is individual Tools used in randomization is flipping a coin. head is considered as control and tail as intervention group. allocation concealment is carrying out

**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**

Mehr street, Ghasrdasht Ave.

**City**

Shiraz

**Province**

Fars

**Postal code**

71959-44315

**Approval date**

2017-10-18, 1396/07/26

**Ethics committee reference number**

IR.SUMS.REC.1396.121

**Health conditions studied****1****Description of health condition studied**

recurrent aphtus stomatitis

**ICD-10 code**

K12.0

**ICD-10 code description**

Recurrent oral aphthae

**Primary outcomes****1****Description**

pain intensity

**Timepoint**

day 0,1,2,3,4,5,6,7

**Method of measurement**

Visual Analogue Scale

**2****Description**

oral lesion size

**Timepoint**

day 0,1,2,3,,4,5,6,7

**Method of measurement**

measuring with ruler

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: In experimental group the patients will receive somaq pills. The patients will use 3pills daily for 7days. By inserting the pill on the lesion, the pill itself will attach to the oral ulcer for some minute. The patient should hold this pill until it solves completely. The pills are 0.9cm in diameter. The pills was prepared by Shiraz Pharmacy Faculty. The compositions of this pill is 50% avicel, 0.2% magnesium Stearate and the remaining is somaq.

**Category**

Treatment - Drugs

## 2

### Description

Control group: In the control group oral paste triadent 3 times in a day will be used. Teriadent is triamcinolone acetone 0.1% manufactured by Raha pharma.co, Isfahan, Iran.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shiraz dental school

**Full name of responsible person**

Fatemeh Lavaee

**Street address**

Mehr street, Ghasrdasht Ave.

**City**

Shiraz

**Province**

Fars

**Postal code**

7195944315

**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**

Basir Hashemi

**Street address**

Mehr street, Ghasrdasht Ave.

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+98 71 3212 2438

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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

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**Email**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Fatemeh Lavaee

**Position**

Associate professo

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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Shiraz University of Medical Sciences

**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**

data related to primary outcome of pain level and size of lesion

**When the data will become available and for how long**

starting 6 months after publication

**To whom data/document is available**

people working in academic institutions people working in businesses

**Under which criteria data/document could be used**

Statistical analysis on data is allowed. The applicant should email a request containing his request and the reason of his request. He should introduce himself. the data will send to him.

**From where data/document is obtainable**

call Dr. Fatemeh Lavaee via lavaeef@sums.ac.ir, fatemeh.lavaee@gmail.com Telephone: 00989177029159

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

The applicant should email a request containing his request and the reason of his request. He should introduce himself. the data will send to him.

**Comments**