

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of effect of sumac spray on minor recurrent aphthous stomatitis treatment

#### Protocol summary

##### Study aim

effect of sumac spray on minor recurrent aphthous stomatitis treatment

##### Design

Clinical trial has a control group, with parallel groups, double-blind, randomized

##### Settings and conduct

This clinical trial study will be conducted on patients with a recurrent aphthous stomatitis attending the oral disease Department of Zahedan Dental School. The first patients group received sumac spray and the patients are asked to take the drug four times a day (one hour before meals and 20 minutes before bedtime) once or twice each time for five days, and avoid drinking or eating for up to half an hour after using the drug. The person will be asked to dry the wound and then use drug at the site of the wound

##### Participants/Inclusion and exclusion criteria

The existence of 1-5 wounds less than 24h with a size of less than 10mm (if there is more than one wound, the average diameter of all wounds will prevail), the pain in the affected area, the age above 18 years, lack of history of drug hypersensitivity, non-pregnant and no lactation, lack of history of systemic disease, non-steroid anti-inflammatory medication or oral antihistamines one month before entering the study, lack of treatment with systemic or immunosuppressive medications a month before entering the study, treatment of wounds with any drug before entering study, lack of treatment with systemic antibiotics 2 weeks before entering the study, the absence of adjacent trauma ulcers caused by sharp tooth edges, broken healing, orthodontic appliance or denture prosthesis

##### Intervention groups

1. control placebo user 2. corticosteroid user

##### Main outcome variables

the effect of sumac spray consumption on recurrent aphthous stomatitis treatment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191012045067N5**

Registration date: **2022-01-01, 1400/10/11**

Registration timing: **prospective**

Last update: **2022-01-01, 1400/10/11**

Update count: **0**

##### Registration date

2022-01-01, 1400/10/11

##### Registrant information

##### Name

masoomeh shirzaiy

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3321 1135

##### Email address

shirzaiy@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-21, 1400/11/01

##### Expected recruitment end date

2022-03-16, 1400/12/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of effect of sumac spray on minor recurrent aphthous stomatitis treatment

#### Public title

Evaluation of effect of sumac spray on minor recurrent aphthous stomatitis treatment

#### Purpose

Health service research

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

The existence of 1-5 wounds less than 24h its size of less than 10mm (if there is more than one wound, the average diameter of all wounds will prevail)the pain existence in the affected area the age above 18 years lack of history of drug hypersensitivity non pregnant and no lactation Lack of history of systemic disease Lack of non-steroid anti-inflammatory medication or oral antihistamines use one month before the study entrance lack of treatment with systemic or immunosuppressive medications a month before the study entrance treatment of wounds with each drug before study entrance lack of treatment with systemic antibiotics 2weeks before the study entrance the absence of aphthea ulcer adjacent trauma ulcers caused by sharp tooth edges, broken restorative , orthodontic appliance or partial denture prosthesis

##### Exclusion criteria:

No attend of person with recurrent aphthous stomatitis in fallow up period non-controlled diabetes non-controlled hypertension pregnancy or lactation active or known infection severe mental disorder require of treatment with antibiotics during the desired treatment

#### Age

From **18 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Outcome assessor

#### Sample size

Target sample size: **30**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

patient and analyzer don't know about drugs and placebo also which one is drug and which one is placebo

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

effectiveness of somac in the treatment of patients with recurrent aphthous stomatitis

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

##### Street address

Azadegan

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9817699693

#### Approval date

2021-09-19, 1400/06/28

#### Ethics committee reference number

IR.ZAUMS.REC.1400.205

## 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

recurrent aphthous stomatitis

#### Timepoint

Day Zero, second, seventh after the start of treatment

#### Method of measurement

Visual Analogue Scale,Periodontal probe

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: People with recurrent aphthous ulcer somac spray 4 times a day for 5 days (The patient asked to use the spraay four times a day (one hour before meals and twenty minutes before bedtime) for five days and half hour after using the drug, Avoid eating and drinking. The person asked to dry the

wound and then use the drug)

**Category**

Treatment - Drugs

**2****Description**

Control group: Control group: People with recurrent aphthous ulcer use placebo 4 times a day for 5 days (The patient asked to use the spray containing essence (placebo) four times a day (one hour before meals and twenty minutes before bedtime) for five days, and half hour after using the drug, Avoid eating and drinking. The person asked to dry the wound and then use the drug)

**Category**

Placebo

**3****Description**

Intervention group: Intervention group: People with recurrent aphthous ulcer use corticosteroid 4 times a day for 5 days(The patient asked to use the orabase containing corticosteroid (triamcinolone) four times a day (one hour before meals and twenty minutes before bedtime) for five days, and half hour after using the drug, Avoid eating and drinking. The person asked to dry the wound and then use the drug)

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Zahedan Dental School

**Full name of responsible person**

Masoomeh Shirzaiy

**Street address**

Azadegan

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9817699693

**Phone**

+98 54 3344 1824

**Email**

Shirzaiy@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Zahedan University of Medical Sciences

**Full name of responsible person**

Mohammadreza Shahraki

**Street address**

Azadegan

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

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+98 54 3344 1824

**Email**

Shirzaiy@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research, Zahedan University of Medical Sciences

**Proportion provided by this source**

10

**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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Masoomeh Shirzaiy

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

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**Email**

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**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Masoomah Shirzaiy

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Masoomah Shirzaiy

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Email**

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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**

manuscript

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

2 year

**To whom data/document is available**

researcher

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

treatment

**From where data/document is obtainable**

internal site

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

search

**Comments**