

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 conducted on patients with a recurrent aphthous stomatis attended to the oral disease Department of Zahedan Dental School ., the first patients group received somac 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 10mmis(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 2weeks 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. cortichosteroid user

Main outcome variables

the effect of somac 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

masoomesh 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		Secondary Ids	empty
Public title	Evaluation of effect of sumac spray on minor recurrent aphthous stomatitis treatment	Ethics committees	<u>1</u>
Purpose	Health service research	Ethics committee	Name of ethics committee
Inclusion/Exclusion criteria			Ethics Committee of Zahedan University of Medical Sciences
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	Street address	Azadegan
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	City	Zahedan
Age	From 18 years old	Province	Sistan-va-Balouchestan
Gender	Both	Postal code	9817699693
Phase	N/A	Approval date	2021-09-19, 1400/06/28
Groups that have been masked	- Participant - Outcome assessor	Ethics committee reference number	IR.ZAUMS.REC.1400.205
Sample size	Target sample size: 30	Health conditions studied	<u>1</u>
Randomization (investigator's opinion)	N/A	Description of health condition studied	recurrent aphthous stomatitis
Randomization description		ICD-10 code	K12.0
Blinding (investigator's opinion)	Double blinded	ICD-10 code description	Recurrent oral aphthae
Blinding description	patient and analyzer don't know about drugs and placebo also which one is drug and which one is placebo	Primary outcomes	<u>1</u>
Placebo	Used	Description	recurrent aphthous stomatitis
Assignment	Parallel	Timepoint	Day Zero, second, seventh after the start of treatment
Other design features	effectiveness of somac in the treatment of patients with recurrent aphthous stomatitis	Method of measurement	Visual Analogue Scale,Periodontal probe
		Secondary outcomes	empty
		Intervention groups	<u>1</u>
		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

Postal code

9817699693

Phone

+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

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City

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Email

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

Masoomeh Shirzaei

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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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