Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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

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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

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City

Zahedan

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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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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 Shirzaiy

Position
Assistant professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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