Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effectiveness of mouth wash containing skin fruit pomegranate extract formulation in the treatment of patients with recurrent aphthous stomatitis

Protocol summary

Study aim

the effectiveness of mouth wash skin fruit pomegranate extract formulation in the treatment of patients with recurrent aphthous

Design

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

Settings and conduct

This clinical trial study was conducted on patients with a recurrent pest disease referred to the oral illnesses Department of Zahedan Dental School equipments., the first group received patientsmouth wash skin fruit pomegranate extract and the patients are asked to take the drug four times a day (one hour before meals and 20 minutes before bedtime) each time one to twoSpray the time for five days, and avoid drinking to eat for up to half an hour after using the drug, avoid eating and drinking. The person will be asked to dry the wound and then spray one to two drugs 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-mouth wash skin fruit pomegranate extract user 2-control placebo user 3- cortichosteroid user

Main outcome variables

the effect ofmouth wash skin fruit pomegranate extract consumption on recurrent aphthous stomatitis treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191012045067N3**
Registration date: **2021-02-07, 1399/11/19**
Registration timing: **retrospective**

Last update: **2021-02-07, 1399/11/19**
Update count: **0**

Registration date

2021-02-07, 1399/11/19

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

2020-11-30, 1399/09/10

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of mouth wash containing skin fruit pomegranate extract formulation in the treatment of patients with recurrent aphthous stomatitis

Public title

the effectiveness of mouth wash skin fruit pomegranate extract formulation in the treatment of patients with recurrent aphthous

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

The existence of 1-5 wounds less than 24h 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 2weeks before entering the study, the absence of adjacent trauma ulcers caused by sharp tooth edges, broken healing, orthodontic appliance or denture prosthesis

Exclusion criteria:

No attend of person with recurrent aphthous stomatitis in fallow up period

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Qualified persons with recurrent aphthous stomatitis in study were randomly divided according to coming time into three groups of pomegranate peel extract mouthwash consumer, placebo and corticosteroid chemical medicine. In this way that the first 10 patients who were qualified of entering study and willing to cooperate entered to study as pomegranate peel mouthwash consumers. After a seven-day course of treatment, the second 10 patients who were qualified and willing to cooperate were evaluated and treated as placebo group. And then again after seven days 10 other patients who were qualified and willing to cooperate were studied to take corticosteroid medicine.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participant and analyzer do not know the type of consumables and the consumables are numbered as 1 , 2

Placebo

Used

Assignment

Parallel

Other design features

effectiveness of mouth wash containing skin fruit pomegranate extract formulation in the treatment of patients with recurrent aphthous stomatitis

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University of Medical Science

Street address

Azadegan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817699693

Approval date

2020-11-01, 1399/08/11

Ethics committee reference number

IR.ZAUMS.REC.1399.401

Health conditions studied

1

Description of health condition studied

the effect of mouth wash containing in recurrent aphthous stomatitis treatment

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:People with recurrent aphthous ulcer use mouth wash containing Pomegranate peel extract 4 times a day for 5 days (The patient asked to spray the mouthwash containing pomegranate peel extract four times a day (one hour before meals and twenty minutes before bedtime) once or twice for five days and half hour after using the drug. Avoid eating and drinking. The person asked to dry the wound and then spray the drug once or twice)
Category
Treatment - Drugs

2

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

3

Description
Intervention People with recurrent aphthous ulcer use corticosteroid 4 times a day for 5 days(The patient asked to spray the mouthwash containing corticosteroid (teriamcinolon) four times a day (one hour before meals and twenty minutes before bedtime) once or twice for five days and half hour after using the drug. Avoid eating and drinking. The person asked to dry the wound and then spray the drug once or twice)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Zahedan Dental School
Full name of responsible person
Masoomeh Shirzaiy
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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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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
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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