

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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- corticosteroid 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

Masoomesh 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

Masoomesh Shirzaiy

Position

Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Azadegan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9817699693
Phone
+98 54 3344 1824
Email
shirzaiy@gmail.com

Person responsible for scientific 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
Azadegan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9817699693
Phone
+98 54 3344 1824
Email
shirzaiy@gmail.com

Person responsible for updating data

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
Azadegan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9817699693
Phone
+98 54 3344 1824
Email
shirzaiy@gmail.com

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