

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Assessment of the effect of mucoadhesive paste of pomegranate on recurrent aphthous stomatitis

Protocol summary

Summary

The main reason for treating recurrent aphthous stomatitis (RAS) is to relieve pain and reduce the frequency of recurrences. The aim of this study is to assess the effect of mucoadhesive paste of pomegranate on recurrent aphthous ulcerations. Materials and Methods: Pomegranate juice is prepared by machine and 5% dried concentration will then added to the paste base. The study is a blind clinical trial. Forty-six patients with RAS formed the study group and will be examined according to pre-established criteria. The patients will be put into two groups. One group will receive paste with drug and the other one will receive mucoadhesive paste without drug. The patients will apply the paste three times a day from the first premonitory signs of RAS appearance. All the patients will be examined on Days 0, 1, 6 and 10. The large diameter of the wound will be measured and recorded by a periodontal probe. Pain intensity will also be calculated using VAS scores. The subjects will be asked to record the intensity of pain every day.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111823169N2**

Registration date: **2015-12-03, 1394/09/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-03, 1394/09/12

Registrant information

Name

Negar Salehi

Name of organization / entity

Department of Oral Medicine of Kerman Dental School

Country

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Recruitment status

Recruitment complete

Funding source

School of Dentistry, Kerman University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of mucoadhesive paste of pomegranate on recurrent aphthous stomatitis

Public title

Effect of pomegranate on recurrent aphthous

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: recurrent aphthous stomatitis; recurring ulcers at least two times yearly. Exclusion criteria: traumatic ulcers caused by a sharp tooth, broken restoration, orthodontic appliances or partial dentures; diseases like anemia; abnormal skin lesions; recurrent infections; recurrent genital ulcerations; joint pain; eye problems and vision disturbances such as pain; blurred vision; redness; patients who were using other medicines

for the treatment of oral aphthous ulcers; oral lesions for more than three days.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Kerman Medical Science university

Street address

Kerman Medical Science Research center, Tahmasbabad squar, Kerman

City

Kerman

Postal code**Approval date**

2011-09-23, 1390/07/01

Ethics committee reference number

k/88/187

Health conditions studied**1****Description of health condition studied**

Medication for Recurrent oral aphthae

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes**1****Description**

Pain intensity

Timepoint

Everyday for 10 days

Method of measurement

visual analogue scale (VAS)

Secondary outcomes**1****Description**

The diameter of the ulcers

Timepoint

The 1st, 6th and 10th days

Method of measurement

Periodontal probe

Intervention groups**1****Description**

Intervention: Pomegranate juice from sweet and sour pomegranate was prepared in equal weight ratio using a juicer. Then, the prepared pomegranate juice was dried by freeze-drying and was added to the mucoadhesive paste with 5% concentration and The paste is administered 3 times daily after breakfast, lunch and before bed on the aphthous ulcers

Category

Treatment - Drugs

2**Description**

Control group: mucoadhesive paste without additives will prepare and The paste is administered 3 times daily after breakfast, lunch and before bed on the aphthous ulcers

Category

Placebo

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

Department of Oral Medicine, Kerman Dental School

Full name of responsible person

Dr Negar Salehi

Street address

Kerman Dental School, Shafa Av.

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Center of Kerman Dental School

Full name of responsible person

Dr Goli Chamani

Street address

Department of Oral Medicine, Kerman Dental School,
Shafa Av.

City

Kerman

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

Yes

Title of funding source

Research Center of Kerman Dental School

Proportion provided by this source**Public or private sector**

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

2

Sponsor

Name of organization / entity

Research Center of Kerman Dental School

Full name of responsible person

Dr Mohamadreza Zarei

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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

Research Center of Kerman Dental School

Proportion provided by this source**Public or private sector**

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Kerman Dental School

Full name of responsible person

Dr Negar Salehi

Position

Oral Medicine Resident

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Fax**Email****Web page address**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty