

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Preparation an herbal oral gel-produced from peel of pomegranate, and clinical study investigating the efficacy of it on patients with recurrent aphthous stomatitis

Protocol summary

Summary

Objective: Recurrent aphthous stomatitis (RAS) is a common complaint of patients. There is a need to funding more natural products that possess therapeutic efficacy targeting aphtaous ulcers. The therapeutic potential of Punica granatum (Pomegranate) has been widely recognized by different cultures. It is speculated that an herbal product from pomegranate peel extract in the form of a gel may be beneficial in treatment of RAS. The aim of this study is to evaluate the efficacy of a gel prepared from pomegranate peel extract (10%) on the clinical management of RAS patients. Design: The present study is a randomized, double-blind, and placebo-controlled study that is conducted on 56 patients diagnosed to have aphtatous ulcers. Setting and conduct: 28 patients were advised to apply pomegranate gel twice times a day for one month and the other 28 patients were given placebo gel for the same duration. Efficacy evaluations are made on the four times during one-month period. Patient exclusion criteria: These include: Drug usage or any treatment occurring before dental treatment; systemic diseases; hypersensitivity history; smoking habits or alcoholism; pregnancy and lactation; orthodontic instruments. Primary outcome measure are duration of healing, size of lesion, pain in lesion and erythema. Data were analyzed using the repeated measures ANOVA, paired and independent t-test. As a result of the few toxic and side effects, and on the other hand, given the antimicrobial, anti-inflammatory, antioxidant effects of the compounds of this product, it is assumed that it can have significant therapeutic effects in the clinical study

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092414106N3**

Registration date: **2017-08-07, 1396/05/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-07, 1396/05/16

Registrant information

Name

Reza Tahvilian

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Science

Expected recruitment start date

2017-07-21, 1396/04/30

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preparation an herbal oral gel-produced from peel of

pomegranate, and clinical study investigating the efficacy of it on patients with recurrent aphthous stomatitis

Public title

Therapeutic effects of oral gel-produced from peel of pomegranate in patients with recurrent aphthous stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Patient exclusion criteria include: Drug usage or any treatment occurring before dental treatment; systemic diseases; hypersensitivity history; smoking habits or alcoholism; pregnancy and lactation; orthodontic instruments.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 56

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**

Ethics committee of Kermanshah University of Medical Science

Street address

Central building, Beheshti Blvd, Kermanshah University of Medical Science

City

Kermanshah

Postal code

6715847141

Approval date

2017-07-05, 1396/04/14

Ethics committee reference number

KUMS.REC.1396.164

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**

duration of healing

Timepoint

one-mounth period

Method of measurement

quantitative and qualitative assays

2**Description**

size of lesion

Timepoint

one-mounth period

Method of measurement

quantitative and qualitative assays

3**Description**

pain in lesion

Timepoint

one-mounth period

Method of measurement

quantitative and qualitative assays

4**Description**

erythema

Timepoint

one-mounth period

Method of measurement

quantitative and qualitative assays

Secondary outcomes

empty

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

Experimental group: In this group, 28 patients will be received 10% Pomegranate gel. The period for use of the product will be twice a day for a period of one month.

Category

2**Description**

Control group: 28 patients will be received placebo. The placebo gels contain all the components of the intervention group gel except for the pomegranate extract; they actually receive the placebo.

Category

Treatment - Drugs

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

Kermanshah University of Medical Science

Full name of responsible person

Mohammad Malmir

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Dental college, Kermanshah University of Medical Science

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Kermanshah University of Medical Science

Full name of responsible person

Reza Tahvilian

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Central building, Beheshti Blvd, Kermanshah University of Medical Science

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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, Kermanshah University of Medical Science

Proportion provided by this source

100

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**

Department of Pharmaceutics, Faculty of Pharmacy, Kermanshah University of Medical Sciences, Kermans

Full name of responsible person

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Position

Ph.D

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Full name of responsible person

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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