Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Name of organization / entity
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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

Treatment - Drugs

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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Science
Full name of responsible person
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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
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Person responsible for updating data

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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