Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation the effectiveness of oral gel containing pomegranate peel extract in treatment of periodontitis

Protocol summary

Study aim
The effect of pomegranate peel extract gel on the treatment of moderate to severe chronic periodontitis

Design
Two arm parallel group with three-blinded postoperative care

Settings and conduct
Patients who come to the dentistry department after examining and filling the consent form, two dental areas considerd with deep pockets in two different quadrants in each patient; then indicators are measured and recorded. Patients with moderate to severe periodontitis are treated with scaling, then, pomogeranet gel is injected into a pocket and placebo is injected into another opcket; then Coe-pack cover each areas and patients are asked to observe their oral health during the study, but refrain from using dental floss and mouthwash in the studied area. The study is three- blinded and participant, researcher, statistical analysor are blind. Drugs are named A and B by the drug manufacturer, so that until the end of the study, she know the contents of the pomegranate gel or placebo of each tube A and B. After one and three months of the initial session, the patient is called and the test indicators are checked.

Participants/Inclusion and exclusion criteria
Patients with moderate to severe periodontitis with the following conditions: the terms of admission to the study are as follows: patients who do not receive other treatments; no history of hypersensitivity reactions; do not using of smoking, and alcohol; not having systemic diseases (such as renal, hepatic, or rheumatic diseases); women who are not pregnant or breastfeeding; not having orthodontic appliance.

Intervention groups
Intervention group: pomegranate peel gel placement in periodontal pockets after scaling. Control group: placebo placement in periodontal pockets after scaling.

Main outcome variables
Pocket depth; plaque index; gingival index; clinical attachment loss; bleeding index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151222025649N6**
Registration date: **2018-10-20, 1397/07/28**
Registration timing: **prospective**

Last update: **2018-10-20, 1397/07/28**
Update count: **0**

Registration date
2018-10-20, 1397/07/28

Registrant information

Name
Masoome Eivazi

Name of organization / entity
Kermanshah University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 83 3822 8397

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-21, 1397/11/01

Expected recruitment end date
2019-06-22, 1398/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation the effectiveness of oral gel containing pomegranate peel extract in treatment of periodontitis

Public title
Evaluation the effectiveness pomegranate peel extract in treatment of gingival inflammation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients with chronic periodontitis that are healthy in terms of systemicity No history of hypersensitivity
Exclusion criteria:
Receive other treatments Tobacco and alcohol consumption Pregnant and nursing women Use of orthodontic appliance

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description
Drugs with A and B are named by the drug manufacturer, so that until the end of the study, she khows the pomegranate gel content or placebo for each tube A and B; In this way researcher and statistical analysor will be blind. The patient have No information about the drug content will be placed on the study sites.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Dentistry school of Kermanshah University of Medical Sciences

Street address
Opposite of the Post office., Shariati Ave

City
Kermanshah

Province
Kermanshah

Postal code
6713954658

Approval date
2018-10-01, 1397/07/09

Ethics committee reference number
IR.KUMS.REC.1397.517

Health conditions studied

1

Description of health condition studied
Moderate to severe chronic periodontitis

ICD-10 code
K05.3

ICD-10 code description
Chronic periodontitis

Primary outcomes

1

Description
Pocket depth

Timepoint
Before intervention, one month after intervention, three months after intervention

Method of measurement
Measuring the distance of pocket base to the gingival with periodontal probe

2

Description
Clinical attachment loss

Timepoint
Before intervention, one month after intervention, three months after intervention

Method of measurement
Measuring the distance of base of pocket from CEJ

3

Description
Gingival index

Timepoint
Before intervention, one month after intervention, three months after intervention

Method of measurement
Determination gingival inflammatory conditions based on observation and comparison

4

Description
Plaque index
Timepoint
Before intervention, one month after intervention, three months after intervention
Method of measurement
Colored surfaces of tooth by disclosing agent

5

Description
Bleeding index
Timepoint
Before intervention, one month after intervention, three months after intervention
Method of measurement
Determination of inflammatory conditions and gingival hemorrhage during probingwith periodontal probe

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The pomegranate peel extract gel in a periodontal pocket in a selected dental quadrant. After scalling all of the teeth with a piezoelectroscopic device in a pre-selected pocket, the pomegranate gel is injected and the area is coverd with coe-pack .the paitent asked to observe their oral health during the course of the study, but refrain from using dental floss and mouthwash in the studied area. Pomegranate and placebo gels produced in the pharmacy of Kermanshah University of Medical Sciences and they are absorbed by periodontal tissues after injection in periodontal pockets.The patient will be monitored for up to three months. The drug has polyphenol compounds such as gallic acid and is present at concentrations 15% and only 3-5ml in a periodontal envelope is injected.
Category
Treatment - Drugs

2

Description
Control group: The placebo in the periodontal pocket of another dental quadrant. This drug is similar to the pomegranate gel without any polyphenols.It is once and about 3-5 milligrams injected in the periodontal pocket of another quadrant. Treatments are same as the intervention group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Periodontics, Dentistry school of Kermanshah University of Medical Science
Full name of responsible person
Masoome Eivazi
Street address
Dentistry school , Shariati Ave ,Shora street
City
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6713954658
Phone
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Farid Najafi
Street address
Ethics Committe of Kermanshah University of Medical Science , Shahidbeheshti Blv
City
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Postal code
6713954658
Phone
+98 83 3722 2400
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m.eivazi@kums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah University of Medical Sciences
Proportion provided by this source
100
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
Kermanshah University of Medical Sciences

Full name of responsible person
Masoome Eivazi

Position
assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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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
The total potential data after being unidentified is shared.

When the data will become available and for how long
Start the access, 6 months after printing the results

To whom data/document is available
All researchers can access the data

Under which criteria data/document could be used
Using of data for use in other similar studies is warranted

From where data/document is obtainable
School of Dentistry, Kermanshah University of Medical Sciences

What processes are involved for a request to access data/document
They can access information upon request from the Kermanshah University of Medical Sciences and receive confirmation.

Comments