

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 considered 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

Masoom Eivazi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 3822 8397

Email address

m.eivazi@kums.ac.ir

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 knows 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 probing with 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 scaling all of the teeth with a piezoelectroscopic device in a pre-selected pocket, the pomegranate gel is injected and the area is covered with coe-pack. The patient 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

Masoom Eivazi

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Dentistry school, Shariati Ave, Shora street

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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 Committee of Kermanshah University of Medical Science, Shahid Beheshti Blv

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Email

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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

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

Masoom 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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Full name of responsible person

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Person responsible for updating data

Contact

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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