

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effect of subgingival irrigation with pomegranate seed extract & chlorhexidine after scaling on chronic periodontitis

Protocol summary

Summary

The aim of this study is to evaluate the efficacy of pomegranate seed extract and compare it with conventional irrigants i.e. chlorhexidine and a control (placebo) group in adjunction to scaling and root planning in chronic periodontitis patient. The participants have at least one tooth with a pocket depth of 5 mm or more. In total, 60 periodontal pockets with a depth of 5 mm or more in each quadrant will be enrolled in the study. The cases having allergy to pomegranate, receiving scaling and root planing or getting antibiotics within the preceding three months and volunteers with any medical condition that may comprise periodontal condition will be excluded from the study. 20 patients with moderate to severe chronic periodontitis will participate in this study. They will be randomly selected from the patients seeking periodontal treatment in the periodontology department of dental school of medical sciences of shiraz university. They will initially complete phase I of the experiment which consists of oral hygiene instructions (OHIs) and mechanical debridement. Subsequently scaling will be performed for all of the patients. Subsequently, one tooth from each quadrant will be chosen and randomly allocated to subgingival irrigation with one of the following solutions: (1) pomegranate seed extract (2) chlorhexidine 0.2 % (3) placebo (distilled water). At baseline and 6 weeks after the final scaling session the following clinical periodontal parameters such as Gingival index (GI) (Loe and sillnes) and bleeding index (BI) (Ienox) and plaque index (PI) (oleary) will be measured. Subgingival irrigation will be done, 4 days after completing of the phase 1 of treatment. After completing of the irrigation periodontal dressing will be placed to the area and removed after 1 week. Subgingival irrigation will be performed 14 days after the first session of the irrigation again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081229308N1**

Registration date: **2016-10-03, 1395/07/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-03, 1395/07/12

Registrant information

Name

Hamed Rezaei

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of subgingival irrigation with pomegranate seed extract & chlorohexidine after scaling on chronic periodontitis

Public title

Evaluation the effect of pomegranate seed oil in the treatment of gum disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with moderate to severe chronic periodontitis; participants have at least one posterior tooth with a pocket depth of 5 mm or more in three different quadrants of the dentition. Exclusion criteria : allergy to pomegranate; smoking habit; overhang restorations; requiring antibiotic prophylaxis prior to dental treatment; doing scaling and root planing or getting antibiotics within the preceding three months; pregnant women; medical condition that may comprise periodontal tissue.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Patients and therapists are not aware of the type of material used so there is double-blind study.

Secondary Ids

empty

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

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Science, Zand Street, Shiraz, Iran

City

Shiraz

Postal code**Approval date**

2016-08-07, 1395/05/17

Ethics committee reference number

IR.SUMS.REC.1395.97

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

Chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

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

periodontal pocket

Timepoint

at baseline - 6 weeks after the final scaling session

Method of measurement

mili meter with Williams probe

2**Description**

gingival index

Timepoint

at baseline - 6 weeks after the final scaling session

Method of measurement

Loe and sillnes score system

3**Description**

bleeding index

Timepoint

at baseline - 6 weeks after the final scaling session

Method of measurement

lenod score system

4**Description**

plaque index

Timepoint

at baseline - 6 weeks after the final scaling session

Method of measurement

in term of percentage by oleary method

Secondary outcomes

empty

Intervention groups

1

Description

intervention group 5 milliliter chlorhexidine 0.2 % solution as subgingival irrigation with insulin syringe gauge 23 after final scalin and root planing

Category

Treatment - Drugs

2

Description

intervention group 5 milliliter pomegranate seed extract as subgingival irrigation with insulin syringe gauge 23 after final scaling and root planing

Category

Treatment - Drugs

3

Description

control group 5 milliliter distilled water used as subgingival irrigation with insulin syringe gauge 23 after final scaling and root planing

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Periodontics, School of Dentistry, Shiraz University of Medical Sciences, Shiraz, Iran

Full name of responsible person

Dr. Farin Kiany Assistant Professor of periodontics

Street address

School of Dentistry, Shiraz University of Medical Sciences, Shiraz, Iran.

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Sayed Basir Hashemi

Street address

Shiraz University of Medical Science, Zand street

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

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

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Zahra Emami

Position

Assistant Professor of periodontics , School of Dentistry, Shiraz University of Medical Sciences

Other areas of specialty/work

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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