

# 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) (lenox) 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3229 6369

##### Email address

rezaei\_h@sums.ac.ir

##### 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

#### Street address

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

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#### Postal code

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#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Dr. Farin Kiany

#### Position

Assistant Professor of periodontics

#### Other areas of specialty/work

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Hamed Rezei

**Position**

Undergraduate Student of dentistry

**Other areas of specialty/work****Street address**

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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*