Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of subgingival irrigation with pomegranate seed extract & chlorohexidine 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.
City
Shiraz
Postal code
Phone
+98 71 3626 4271
Fax
Email
Emamiz@sums.ac.ir
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
Street address
Department of Periodontics, School of Dentistry, Shiraz University of Medical Sciences, Shiraz, Iran.
City
Shiraz
Postal code
Phone
+98 71 3626 4271
Fax
Email
Kianif@sums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Hamed Reazei

Position
Undergraduate Student of dentistry

Other areas of specialty/work

Street address
School of Dentistry, Shiraz University of Medical Sciences, Shiraz, Iran

City
Shiraz

Postal code

Phone
+98 71 3626 4271

Fax

Email
rezaei_h@sums.ac.ir

Web page address

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