

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparision of the effects of Flower Punica Granatum and Rhus Coriaria Mouthwashes with Cholorhexidine Mouthwash on periodontal indices in 16-25 year fixed orthodontic female patients

Protocol summary

Summary

This study aimed to compare the effects of Punica granatum (PG) and Rhus coriaria (RC) mouthwashes with those of chlorhexidine (CHX), the gold standard, on periodontal parameters in fixed orthodontic patients. This cross over double blinded randomized clinical trial study was conducted on 42 female (16 - 25 years), who were undergoing fixed orthodontic treatment and presenting to the Orthodontics Department of Shahid Beheshti University and Behfar Clinic . Then patients were divided randomly into four groups. Lobene, Bay and Ainamo, O'leary indeces have been recorded before treatment, after using first mouthwash, then after serum as a placebo, and finally after second mouthwash. In group 1, at first cholorhexidine mouthwash, then flower Punica Granatum mouthwash was prescribed. In group 2, at first cholorhexidine mouthwash, then Rhus Coriaria mouthwash was prescribed. In group 3, at first Rhus Coriaria mouthwash, then cholorhexidine mouthwash was prescribed. In 4, group at first flower Punica Granatum mouthwash, then cholorhexidine mouthwash was prescribed. Each mouthwash was used for 28 days. Patients used 15mL of 0.2% CHX mouthwash twice daily each time for 30 seconds.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031817061N1**

Registration date: **2014-07-29, 1393/05/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-07-29, 1393/05/07

Registrant information

Name

Elahe Vahid Dastjerdie

Name of organization / entity

Dental University of Shahid Beheshti

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Dental University of Shahid Beheshti

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of the effects of Flower Punica Granatum and Rhus Coriaria Mouthwashes with Cholorhexidine Mouthwash on periodontal indices in 16-25 year fixed orthodontic female patients

Public title

Comparision of the effects of Flower Punica Granatum and Rhus Coriaria Mouthwashes with Cholorhexidine Mouthwash on periodontal indices in 16-25 year fixed orthodontic female patients

Purpose

Other

Inclusion/Exclusion criteria

42 female 16 - 25 years subjects with full fixed orthodontic treatment ;absence of extensive carious lesions ; no dental calculus ; having a minimum score of 1 in Lobene's MGI ; having a minimum score of 1 in GBI by Bay and Ainamo ; gingival sulcus depth of ≤ 3 mm ; no history of corticosteroid therapy in the past three months ; no antibiotic therapy in the past six months ; no systemic disease ; no history of periodontal disease or periodontal surgery ; no history of using mouthrinses for 10 consecutive days in the past three months ; no history of allergy to mouthrinses ; no pregnancy or nursing ; and no cigarette smoking.

Age

From **77 years** old to **69 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences ,
Daneshju Blvd,Velenjak St

City

Tehran

Postal code

Approval date

2014-02-25, 1392/12/06

Ethics committee reference number

116/5376

Health conditions studied

1

Description of health condition studied

Periodontal Indexes in Fix Orthodontic Patients

ICD-10 code

K05

ICD-10 code description

Gingivitis and Periodontal Diseases

Primary outcomes

1

Description

lobene index

Timepoint

28 days

Method of measurement

colour observe of margin and papilla of gingival

2

Description

Bay and Ainamo index

Timepoint

28 days

Method of measurement

probing in salcus.evalute bleeding or not after 10 sec

3

Description

O'leary index

Timepoint

28 days

Method of measurement

use of disclosing solution

Secondary outcomes

empty

Intervention groups

1

Description

Chlorhexidin Mouthwash 0.2% : Patients used 15mL ,
twice daily each time for 30 seconds.

Category

Treatment - Drugs

2

Description

Punica Granatum Mouthwas: Patients used 15mL , twice
daily each time for 30 seconds.

Category

Treatment - Drugs

3

Description

Rhus Coriari Mouthwas: Patients used 15mL , twice daily each time for 30 seconds.

Category

Treatment - Drugs

4

Description

Serum Mouthwash Patients used 15mL , twice daily each time for 30 seconds.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental University of Shahid Beheshti

Full name of responsible person

Dr.Elahe Vahid Dastjerdie

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Behfar Clinic

Full name of responsible person

Dr.Elahe Vahid Dastjerdie

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dental University of Shahid Beheshti

Full name of responsible person

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Dental University of Shahid Beheshti , Daneshju Blvd ,Velenjak St

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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

Dental University of Shahid Beheshti

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

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Full name of responsible person

Zahra Shadkar

Position

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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