

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

A clinical trial for comparison the effect of two mouthwashes, Persica and Chlorhexidine, on surface characterization and static friction between wire and bracket in orthodontic patients.

Protocol summary

Summary

Title: A clinical trial for comparison the effect of two mouthwashes, Persica and Chlorhexidine, on surface characterization and static friction between wire and bracket in orthodontic patients Objectives: Evaluation and comparison of changes in surface roughness and friction of orthodontic wires and brackets with Chlorhexidine and Persica mouthwashes Design: Interventional Setting and conduct: Three groups composed of 20 orthodontic patients who have inclusion criteria, at certain stage of treatment will be assumed as Persica group, Chlorhexidine group and control group. Chlorhexidine Group: Twenty stainless steel 0.019*0.025 inch orthodontic arch wires and 20 additional stainless steel brackets in the correct stage of treatment will be inserted in fixed orthodontic appliance. Chlorhexidine mouthwash will be prescribed according to anti inflammatory regiment. A predetermined amount of the mouthwash will be used twice daily for two weeks. Each rinsing time is set 30 seconds. After day 14, the patient will be visited and the wire with the bracket, which is just ligated to the wire, will be removed. The wire will be replaced with an appropriate wire. Persica Group: Twenty stainless steel 0.019*0.025 inch orthodontic arch wires and 20 additional stainless steel brackets in the correct stage of treatment will be inserted in fixed orthodontic appliance. Persica mouthwash will be prescribed according to current hygienic protocols and previous studies. The patient will be educated to dissolve 15 cc of the mouthwash in 15 cc water, completely shake and then rinse for 30 seconds. After day 14, the patient will be visited and the wire with the bracket will be removed. The wire will be replaced with an appropriate wire. To omit the abrasive effects of oral hygiene care materials, a similar toothpaste and interdental brush will be given to each patient. Control Group: Twenty stainless steel 0.019*0.025 inch orthodontic arch wires and 20

additional stainless steel brackets in the correct stage of treatment will be inserted in fixed orthodontic appliance. In this group, after insertion of brackets and wires, only toothpaste and toothbrushes will be given to patients for daily oral hygiene care. After day 14, the patient will be visited and the wire with the bracket will be removed. The wire will be replaced with an appropriate wire. The wires and brackets, after removal, will be cleaned with ethanol alcohol and a cotton roll. Insertion and removal of the wires and brackets will be performed by one clinician. Surface characterization of brackets and wires, after applying ultrasonic, will be assessed before and after the intervention. Static friction between wire and brackets will be assessed with Universal Testing Machine. Surface characterization of wires and brackets will be assessed with Atomic Force Microscope and Scanning Electron Microscope respectively. Major inclusion and exclusion criteria: Inclusion criteria: Ability to control oral hygiene. Exclusion criteria: Metabolic and systemic diseases; Salivary gland diseases; Consuming medications that affect amount or consistency of saliva; Consuming any other mouthrinse; Cigarette smoking; Drug abusing; Pregnancy or breast feeding. Interventions: Chlorhexidine and Persica mouthwashes Main outcome measures (variables): 1. Surface characterization of orthodontic wire 2. Surface characterization of brackets 3. Static friction between orthodontic wire and bracket

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2014032117067N1**

Registration date: **2014-09-03, 1393/06/12**

Registration timing: **prospective**

Last update:

Update count: 0

Registration date
2014-09-03, 1393/06/12

Registrant information

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Elham sadat Emadian razavi

Name of organization / entity
Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2014-12-31, 1393/10/10

Expected recruitment end date
2015-12-31, 1394/10/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A clinical trial for comparison the effect of two mouthwashes, Persica and Chlorhexidine, on surface characterization and static friction between wire and bracket in orthodontic patients.

Public title
Evaluation the effect of two mouthwashes on surface characterization of orthodontic wire and bracket and friction between bracket and wire

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Ability to control oral hygiene.
Exclusion criteria: Metabolic and systemic diseases; Salivary gland diseases; Consuming medications that affect amount or consistency of saliva; Consuming any other mouthrinse; Cigarette smoking; Drug abusing; Pregnancy or breast feeding

Age
No age limit

Gender
Both

Phase
2-3

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
Not used

Assignment
Parallel

Other design features
In order to randomized assignment of samples, three folded paper cards were used.

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Enqelab Square, Tehran University of Medical Sciences

City
Tehran

Postal code

Approval date
2014-05-05, 1393/02/15

Ethics committee reference number
92-03-70-23963-106585

Health conditions studied

1

Description of health condition studied
Surface characterizations of orthodontic wire and bracket and static friction between wire and bracket in dry state

ICD-10 code
T78.8

ICD-10 code description
Other adverse effects, not elsewhere classified

Primary outcomes

1

Description
Surface characterization of orthodontic wire

Timepoint
Two weeks

Method of measurement
Atomic Force Microscope

2

Description
Surface charachterization of brackets

Timepoint

Two weeks

Method of measurement

Scanning Electron Microscope

3**Description**

Static friction between orthodontic wire and bracket

Timepoint

Two weeks

Method of measurement

Universal Testing Machine

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention name: Chlorhexidine gluconate 0.2%
Administration: The mouth is rinsed with 30 ml (2 Tablespoons) of undiluted chlorhexidine twice daily (morning and night) for 30 seconds after brushing for two weeks. Individuals must expectorate the chlorhexidine after rinsing and must not rinse their mouths with water or mouthwashes, brush their teeth, or eat immediately after using chlorhexidine. Patients should clean their teeth with Oral-B tooth brush and Crest, Gum Protection tooth paste.

Category

Treatment - Drugs

2**Description**

Intervention name: Persica Administration: The mouth is rinsed with 30 ml (2 Tablespoons) of diluted Persica (15 mlit Persica and 15 mlit water), twice daily (morning and night) for 30 seconds after brushing for two weeks. Patients should clean their teeth with Oral-B tooth brush and Crest, Gum Protection tooth paste.

Category

Treatment - Drugs

3**Description**

Control: Active control Patients should clean their teeth with Oral-B tooth brush and Crest, Gum Protection tooth paste.

Category

N/A

Recruitment centers**1****Recruitment center**

Name of recruitment center

Orthodontic Department, Dental School, Tehran

University of Medical Sciences

Full name of responsible person

Mrs. Saeedeh Sharafi

Street address

North Kargar St., Dental School

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Ms. Elahe Alamdar

Street address

Enqelab St., Tehran University of Medical Sciences,
Dental Research Center

City

Tehran

Grant name**Grant code / Reference number**

-

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

Yes

Title of funding source

Tehran 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**

Department of Orthodontics, Faculty of Dentistry,
Tehran University of Medical Sciences

Full name of responsible person

Elham sadat Emadian Razavi

Position

Assistant of Orthodontics

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Tahereh Hosseinzadeh Nik

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Professor

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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