

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Effect of Chlorhexidine and fluoride-containing mouthwashes on salivary metal ions in patients treated with fixed orthodontic appliances: An in-vivo study

Protocol summary

Summary

The aim of this study was to evaluate effect of Chlorhexidine and containing fluoride mouthwashes on the salivary metal ions release in the patients with fixed orthodontic appliances. The study design is double-blind, randomized clinical trial and In-Vivo. 45 patients were selected with following criteria: patients with indication of orthodontic treatment in both jaw and absence of metal restoration in their mouth. After obtaining informed consent from patients, The first stage of sampling (5ml unstimulated saliva was collected) before Bonding orthodontic brackets and tubes is done. and the amount of nickel and chrome metal ions were analyzed using an atomic absorption spectrophotometer method. then, The samples with stainless steel brackets and tubes in both jaw bonded and were randomly divided into three groups: 1) received Chlorhexidine 0/12% Mouthwash. 2) received containing Fluoride Oral-B Mouthwash. 3) Patients take a water as a placebo. It is recommended that people use Mouthwashes for a month and twice in a day. Every time kept in their mouth for 30 seconds. Then second stage of sampling was carried out and About 5ml of saliva are obtained and sent to the laboratory for nickel and chrome metal ions measurements. The findings of this study can be used to select suitable mouthwash with minimum biological side effects

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041531250N3**
Registration date: **2017-11-01, 1396/08/10**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-01, 1396/08/10

Registrant information

Name

Fariborz Amini

Name of organization / entity

Islamic Azad University Of Medical Science Dental School

Country

Iran (Islamic Republic of)

Phone

+98 21 2212 1619

Email address

f_amani@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Dental School of Hormozgan

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Chlorhexidine and fluoride-containing mouthwashes on salivary metal ions in patients treated with fixed orthodontic appliances: An in-vivo study

Public title

Ion release from orthodontic brackets in 2 mouthwashes

Purpose

Prevention

Inclusion/Exclusion criteria

The criteria for selection: the patients with 12-30 years of age have a indication of orthodontic treatment in both jaw. Patients with no systemic diseases Do not smoke or drink alcohol do not have a Previously orthodontic treatment . absence of any metal restorations like an amalgam restorations or a metal crowns.

Age

From **12 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Dental Branch of Islamic Azad University of Tehran

Street address

No.4,neyestan10,Pasdaran St,Tehran

City

tehran

Postal code

Approval date

2018-03-13, 1396/12/22

Ethics committee reference number

86/12953

Health conditions studied

1

Description of health condition studied

the patients treated with fixed orthodontic appliances

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Chrome metal ion

Timepoint

before bonding brackets and tubes-a month after using mouthwashes

Method of measurement

Atomic Absorbtion

2

Description

Nickel metal ion

Timepoint

before bonding brackets and tubes-a month after using mouthwashes

Method of measurement

Atomic Absorbtion

Secondary outcomes

empty

Intervention groups

1

Description

intervention group:containing fluoride Oral-B Mouthwash (Procter & Gambl, Weybridge, United Kingdom) for a month and use twice in a day. Every time kept in the mouth for 30 seconds.

Category

Treatment - Drugs

2

Description

control group: the patients use a water as a placebo) for a month and use twice in a day. Every time kept in the mouth for 30 seconds.

Category

Treatment - Drugs

3

Description

intervention group: Chlorhexidine 0/12% Mouthwash (Emadpharma Labratories, Tehran, Iran) for a month and use twice in a day. Every time kept in the mouth for 30 seconds.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

department of Orthodontics Dental Branch of Islamic Azad University of Tehran

Full name of responsible person

mahsa mohammadzadeh

Street address**City**

tehran

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

ental Schools of Hormozgan

Full name of responsible person

mahsa mohammadzadeh

Street address

Bandar Abbas, Research center of dentistry school

City

Bandar Abbas

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

ental Schools of Hormozgan

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**

Dental Branch of Islamic Azad University of Tehran

Full name of responsible person

mahsa mohammadzadeh

Position

postgraduate student

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

No.4,neyestan10,Pasdaran St,Tehran

City

Tehran

Postal code**Phone**

+98 21 2256 4571

Fax**Email**

mmzadeh66@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Dental Branch of Islamic Azad University of Tehran

Full name of responsible person

fariborz amini

Position

Professor

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

No.4,neyestan10,Pasdaran St,Tehran

City

Tehran

Postal code**Phone**

+98 21 2256 4571

Fax**Email**

f_amini@dentaliau.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Dental Branch of Islamic Azad University of Tehran

Full name of responsible person

mahsa mohammadzadeh

Position

postgraduate student

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

No.4,neyestan10,Pasdaran St,Tehran

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Tehran

Postal code**Phone**

+98 21 2256 4571

Fax**Email****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