

# 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

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##### 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

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**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

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

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**Full name of responsible person**

mahsa mohammadzadeh

**Position**

postgraduate student

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

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**Postal code****Phone**

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**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*