Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Oct 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 Sciense Dental School
Country
Iran (Islamic Republic of)
Phone
+98 21 2212 1619
Email address
f_amini@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 with12-30 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
City
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