Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Effect of flouride mouthwash and tooth-mousse paste usage on ion release and PH of soliva in patients undergoing fixed orthodontic treatment

Protocol summary

Study aim

The elevated levels of metals in saliva are thought to occur by corrosion of the chemical elements in the alloys. The aim of this study was to compare the effect of fluoride-containing mouthwash and amorphous calcium phosphate phosphopeptide casein paste on the release of ions from orthodontic fixed devices in saliva of patients undergoing orthodontic treatment and PH of saliva.

Design

A randomized, double blinded clinical trial with a parallel group design of 36 patients will be enrolled between september and december 2019.

Settings and conduct

Saliva samples from all patients are taken at three different time points: before orthodontic treatment, 1 month after appliance placement, 2 months after appliance placement. salivary samples was analyzed by atomic absorption spectrophotometer. This measurements will be performed at Kerman Universitu of Medical Sciences stem cell research center.

Participants/Inclusion and exclusion criteria

This study will be conducted on 36 people who want fix orthodontic treatment and volunteer to participate in this study. These people have no history of systemic disease, no caries or active periodontal disease and are in permanent dental phase. They do not have any metal crowns, bridges or any nickel and chromium restorations in their mouth.

Intervention groups

Patients will be divided into 3 groups of 12 and all will receive health education. There will be no special intervention for control group but people in the second group are asked to use ACP-CPP paste on there teeth twice a day after brushing and people in the third group are asked to spoon 15 ml of flouride mouthwash into their mouths for 30 seconds.

Main outcome variables

The concentration of nickel and chromium in the saliva is measured in ng/ml(PPB equivalent). The correlation between the salivary PH of patients and the concentration of ions in different groups is compared.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190827044632N1**
Registration date: **2019-10-05, 1398/07/13**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-05, 1398/07/13**
Update count: **0**

Registration date

2019-10-05, 1398/07/13

Registrant information

Name

Behnoush Hormozi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of flouride mouthwash and tooth-mousse paste usage on ion release and PH of soliva in patients undergoing fixed orthodontic treatment

Public title
Effect of flouride mouthwash and tooth-mousse paste on fixed orthodontic appliances
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
No history of systemic disease Lack of dental Caries Absence of active periodontal disease Patients in Permanent dental stage No metal crowns, bridge or any nickel and chromium restorations in the patient's mouth The patient does not have previous orthodontic treatment
Exclusion criteria:
Patient with cleft lip or palate or any type of oral syndrome Evolutionary enamel lesions Multiple dental restorations History of allergy to milk proteins Use of antibiotics during the study Oral breathing Smokers
Age
From **12 years** old to **30 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Each patient is assigned a number based on a random number table obtained by using a computer software (NCSS, Kaysville, UT, USA). Details of different groups are stored on cards and in sealed envelopes that are similar in appearance and have their own group contents. These envelops are numbered by an independent individual and assigned to patients based on the number of them.
Blinding (investigator's opinion)
Double blinded
Blinding description
Each patient receives a packet containing the health contents of their group. Once the study volunteer has been evaluated by the lead researcher and his/her compliance with the inclusion criteria has been confirmed, the envelope dedicated to the patient will be opened by a senior resident in the field of orthodontics and the study process will begin.

Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran National Committee For Ethics In Biomedical Research
Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafshan & South Falamak, Qods Town, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1467664961
Approval date
2019-07-29, 1398/05/07
Ethics committee reference number
IR.KMU.REC.1398.243

Health conditions studied

1

Description of health condition studied
Ion release and PH of soliva during use of different remineralizing agents in patients undergoing fixed orthodontic treatment
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The rate of release of nickel ion
Timepoint
Before orthodontic treatment, 1 month and 2 month after orthodontic treatment
Method of measurement
Atomic absorption spectrophotometer

Secondary outcomes

1

Description

The rate of release of chromium ion

Timepoint

Before orthodontic treatment, 1 month and 2 month after orthodontic treatment

Method of measurement

Atomic absorption spectrophotometer

Intervention groups

1

Description

Control group: All patients are instructed to brush their teeth twice a day for 3 minutes using 1450 ppm fluoride toothpaste. They are asked not to use any oral hygiene products or instruments, including Oral irrigators or antimicrobial mouthwashes, during the study.

Category

Lifestyle

2

Description

Intervention group: Following health training similar to group 1, Patients were asked to place 5 mm of ACP-CPP cream (GC Tooth Mousse, Asia Pty. Ltd, Japan) twice a day after brushing on their tooth surfaces and they were advised to keep the paste on the surface of their teeth for at least 3 minutes before washing their mouths. Patients should not take any food or drink for 30 minutes after using CPP-ACP paste, and any other fluoride supplement is not permitted.

Category

Prevention

3

Description

Intervention group: Patients are instructed to rinse 15 ml fluoride in their mouths for 30 seconds twice a day after brushing, and then refrain from eating, drinking and washing for 30 minutes.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Kerman University of Medical Sience

Full name of responsible person

Behnoush Hormozi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

molook Torabi

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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

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Behnoush Hormozi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
only part of the data, such as the main outcome information, can be shared.

When the data will become available and for how long
6 month after the results are published

To whom data/document is available
researchers working in academic institutions

Under which criteria data/document could be used
For review in academic and scientific environments

From where data/document is obtainable
behnoosh.hormozy@gmail.com

What processes are involved for a request to access data/document
As soon as posible

Comments