

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of the effect of brackets coated with titanium dioxide nanoparticles in the prevention of dental enamel demineralization and the amount of titanium release in the oral environment during the treatment of fixed orthodontic patients: a randomized controlled clinical trial

Protocol summary

Study aim

Determining the effect of brackets coated with titanium dioxide nanoparticles in water on the demineralization of tooth enamel and the amount of saliva release in the oral environment during the treatment of fixed orthodontic patients.

Design

Clinical trial with a single-blind, randomized phase 0 control group on 48 patients. To determine the intervention and control groups, pre-prepared cards were drawn from the box by lot.

Settings and conduct

This study will be conducted by orthodontic assistants in the orthodontic department of Hamedan University of Medical Sciences. One maxillary lateral tooth in one person will be randomly selected as a control and one lateral tooth in another person as an intervention, and brackets coated with nanoparticles will be placed on the teeth of the intervention group. The bonding therapist and the participants are unaware of the intervention and control groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: Fixed orthodontic treatment candidates who are 15-25-year-old with upper lateral teeth, without cracks, demineralization. Exclusion criteria: patients who have lost their teeth due to caries.

Intervention groups

One maxillary lateral tooth in one person is randomly bonded with brackets coated with nanoparticles. In the control group, one maxillary lateral tooth is randomly bonded with a normal orthodontic bracket (without nanoparticles). Two groups of 0/022 inch MBT system bracket (American brand) will be used.

Main outcome variables

Demineralization of dental enamel

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140215016582N7**

Registration date: **2024-01-08, 1402/10/18**

Registration timing: **prospective**

Last update: **2024-01-08, 1402/10/18**

Update count: **0**

Registration date

2024-01-08, 1402/10/18

Registrant information

Name

Vahid Mollabashi

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 3835 2555

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-20, 1402/10/30

Expected recruitment end date

2024-07-20, 1403/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of brackets coated with titanium dioxide nanoparticles in the prevention of dental enamel demineralization and the amount of titanium release in the oral environment during the treatment of fixed orthodontic patients: a randomized controlled clinical trial

Public title

Effect of brackets coated with nanoparticles in the prevention of dental enamel demineralization

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient ranged 15-25 years old The ability to observe the hygiene of mouth They must have 1-4 repaired yeeth A healthy and flawless immune system Non-use of antibiotics and antibacterial during treatment

Exclusion criteria:

Tooth loss due to decay The presence of active caries or prosthetic treatment in the mouth Smoking Periodontal disease Treated with immunosuppressive drugs People with diabetes Pregnancy

Age

From **15 years** old to **25 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study simple randomization method will be used.24 cards with a/b code and 24 cards with b/a code will be provided in a box, in which the patient will randomly select from. the codes' key is with the first investigator.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the participants, the therapists who bond the brackets, the researcher who measures the diagnodent number, and the analyzing researcher are unaware of the group assignment.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Hamadan university of medical sciences

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Şahid Fahmideh Street

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Postal code

6517838695

Approval date

2023-11-25, 1402/09/04

Ethics committee reference number

IR.UMSHA.REC.1402.557

Health conditions studied**1****Description of health condition studied**

Caries and demineralization

ICD-10 code

K02.61

ICD-10 code description

Dental caries on smooth surface limited to enamel

Primary outcomes**1****Description**

Tooth demineralization

Timepoint

Before the intervention, one month and three months after the intervention

Method of measurement

Diagnodent device

Secondary outcomes**1****Description**

The amount of titanium in saliva

Timepoint

Before the intervention, one month and three months after the intervention

Method of measurement

ICP MS device

Intervention groups

1

Description

Intervention group: Intervention group: tooth bond with bracket coated by titanium dioxide nanoparticles with vapor deposition method

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan university of medical sciences

Full name of responsible person

Behrooz Khodabandehloo

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice Chancellor for Research and Technology, Hamedan University of Medical Science

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

Hamedan University of Medical Sciences

Full name of responsible person

Behrooz Khodadandehloo

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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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

Not applicable

Title and more details about the data/document

Some data such as information on the main outcome

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Only available for people working in academic institutions

Under which criteria data/document could be used

For some study designs

From where data/document is obtainable

velayateallah@gmail.com 00989187029713

What processes are involved for a request to access data/document

The study will last about 6 months and then the result will be published in the form of an article 2 months later.

Comments