

# 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)

##### Phone

+98 81 3835 2555

##### Email address

mollabashi@umsha.ac.ir

##### 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

**Street address**

Şahid Fahmideh Street

**City**

Hamadan

**Province**

Hamadan

**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

#### Street address

Shahid Fahmideh

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838695

#### Phone

+98 81 3252 0182

#### Email

Webda@umsha.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

Dr Saeed Bashirian

#### Street address

Shahid Fahmideh

#### City

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#### Province

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6517838677

#### Phone

+98 81 3838 1059

#### Email

Webda@umsha.ac.ir

#### 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

Dentistry

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#### Province

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Velayateallah@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

Behrooz Khodabandehloo

#### Position

Resident

#### Latest degree

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#### Other areas of specialty/work

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Behrooz Khodabandehloo

**Position**

Resident

**Latest degree**

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**Email**

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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**