

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Evaluation the effect of orthodontic adhesive containing titanium dioxide and chitosan nano-particles on mineral content and streptococcus mutans population in fixed orthodontic patients

#### Protocol summary

##### Study aim

Evaluation the effect of orthodontic adhesive containing titanium dioxide and chitosan nano-particles on mineral content and streptococcus mutans population in fixed orthodontic patients

##### Design

A randomized, double blinded, controlled clinical trial with parallel groups.

##### Settings and conduct

This clinical trial study will be conducted on 50 patients undergoing orthodontic treatment, who have been referred to orthodontic clinic of Mashhad Dental School (Responsible person: Dr. Fahimeh Farzanegan). Then, they will be randomly assigned to the case group and control group. In control group to attach the brackets, a light cure composite will be used. In the case group, 5% by weight of titanium dioxide nanoparticles and 5% by weight nanocytosine will be added to the composite. After the set up, daily oral hygiene is recommended three times a day. Measurement of the enamel content and sampling for microbiological testing will be done at 24, 2, 6 months after bonding.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Orthodontic patients aged between 13-18 years undergoing fixed orthodontic treatment Healthy gum Upper second premolars and upper lateral incisors of the participants to be free of macroscopic enamel cracks, caries, or enamel hypoplasia. Exclusion criteria: Patients taking medications that cause xerostomia. Systemic disease and active periodontal disease Active caries on at least one tooth

##### Intervention groups

In the control group, light cure composite (Transbond XT, 3M, USA) will be used to bond brackets. In the case group, 5% by weight of titanium dioxide nanoparticles and 5% by weight nanocytosine will be added to the composite.

#### Main outcome variables

Number of streptococcal bacteria surrounding lateral brackets; Amount of mineral content of enamel

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180826040866N1**

Registration date: **2018-11-15, 1397/08/24**

Registration timing: **prospective**

Last update: **2018-11-15, 1397/08/24**

Update count: **0**

##### Registration date

2018-11-15, 1397/08/24

##### Registrant information

##### Name

Fahimeh Farzanegan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3841 1796

##### Email address

farzaneganf@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-20, 1397/12/01

##### Expected recruitment end date

2019-05-22, 1398/03/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation the effect of orthodontic adhesive containing titanium dioxide and chitosan nano-particles on mineral content and streptococcus mutans population in fixed orthodontic patients

**Public title**

Evaluation the efficacy of orthodontic adhesive containing titanium dioxide and chitosan nano-particles in fixed orthodontic patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Orthodontic patients aged between 13-18 years undergoing fixed orthodontic treatment Healthy gum Upper second premolars and upper lateral incisors of the participants to be free of macroscopic enamel cracks, caries, or enamel hypoplasia.

**Exclusion criteria:**

Patients taking medications that cause xerostomia. Systemic disease or active periodontal disease Active caries on at least one tooth

**Age**

From **13 years** old to **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Method of randomization will be simple and will be accomplished using the table of random numbers. Allocation concealment will be achieved with sequentially numbered, opaque, sealed envelopes containing the treatment allocation cards. Baseline information will be written on the outside before opening the envelope. The project manager will be responsible for opening the next envelope in sequence and implementing the randomization process.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The patients do not know that they are in the control group or the intervention group and the composites used in tubes with the same and encoded shapes that the

clinician does not know about. Finally, the sampling is also coded to allow the data analyzer to be blinded to the study.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Mashhad University of Medical Sciences

**Street address**

Azadi Square, Mashhad Dental School

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9185836393

**Approval date**

2018-09-23, 1397/07/01

**Ethics committee reference number**

IR.MUMS.DENTISTRY.REC.1397.050

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

Demineralization of tooth enamel

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Population of Sterptococcus Mutans

**Timepoint**

24 hours, 2 months and 6 months after placing brackets

**Method of measurement**

Real-time polymerase chain reaction

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

Determination of mineral context of enamel

**Timepoint**

24 hours, 2 months and 6 months after placing brackets  
**Method of measurement**  
Quantitative laser fluorescence technique

## Intervention groups

### 1

#### Description

Intervention group: In this group, for bonding brackets the composite (Transbond XT, 3M, USA), which adds 5% by weight of titanium dioxide nanoparticles and 5% by weight of nanochitosan will be used.

#### Category

Prevention

### 2

#### Description

Control group: In this group, for bonding of brackets the composite (Transbond XT, 3M, USA) will be used.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mashhad Dental School

##### Full name of responsible person

Fahimeh Farzanegan

##### Street address

Vakilabad blvd, Park Square, Mashhad Dental School

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9185836393

##### Phone

+98 51 3882 9501

##### Email

farzaneganf@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohsen Tafaghodi

##### Street address

Research chancellor of Mashhad University of Medical Sciences, Daneshgah street no. 18

##### City

Mashhad

##### Province

Razavi Khorasan

#### Postal code

9177899191

#### Phone

+98 51 3841 2081

#### Email

tafaghodim@mums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Fahimeh Farzanegan

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

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Vakilabad blvd, Park Square, Mashhad Dental School

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mashhad University of Medical Sciences

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**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Data of our tests will be available after deidentification.

**When the data will become available and for how long**

Starting 6 months after publication

**To whom data/document is available**

Data is only available for people working in academic institutions

**Under which criteria data/document could be used**

Data is available for performing systematic reviews and meta analysis

**From where data/document is obtainable**

The applicant should send an mail to corresponding author(Fahimeh Farzanegan) to get the data files.  
farzaneganf@mums.ac.ir

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

After sending email by applicant it will be replied until one week.

**Comments**