

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

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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

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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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Person responsible for scientific inquiries

Contact

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Mashhad University of Medical Sciences

Full name of responsible person

Fahimeh Farzanegan

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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