

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Nano hydroxyapatite containing tooth paste on enamel demineralization during the first six months of fixed orthodontic treatment- A triple-blind randomized clinical trial

Protocol summary

Study aim

The objective of the present study is to discover the preventive effects of Nanohydroxyapatite toothpaste on enamel demineralization.

Design

This will be a triple-blind randomized controlled trial with a 1:1 allocation ratio and 2 parallel groups, examining the superiority of Nano hydroxyapatite containing toothpaste for preventing enamel demineralization during fixed orthodontic treatment compared with fluoride containing toothpaste.

Settings and conduct

The trial will be triple-blinded. Both the participants and clinician will be masked to group allocation and they will not be aware of the type of toothpaste. The person who uses DIAGNOdent to measure the enamel demineralization is also unaware of how individuals are assigned to the groups. Furthermore, the individual analyzing the data will be unaware of the study protocol.

Participants/Inclusion and exclusion criteria

The inclusion criteria: (1) need for comprehensive orthodontic treatment by fixed appliances at least in the upper arch; (2) permanent dentition; (3) no plaque accumulation or gingival inflammation before bracket bonding; (4) good general health. The exclusion criteria: patients with smoking habit, tooth anomalies and active dental caries.

Intervention groups

Before treatment, patients in the experimental and control groups will be trained to maintain oral hygiene (according to a form prepared for this purpose) and brush 3 times a day with Nano hydroxyapatite and white fluoride (Colgate, Colgate-Palmolive Co. New York, New York, United states) toothpaste respectively. All patients will be instructed to brush their teeth by soft toothbrush and interdental brush. The patient will be reviewed every 4 to 6 weeks.

Main outcome variables

The goal is to evaluate the preventive effect of Nano hydroxyapatite containing tooth paste on enamel demineralization during the first six months of fixed orthodontic treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191127045518N2**

Registration date: **2021-09-13, 1400/06/22**

Registration timing: **prospective**

Last update: **2021-09-13, 1400/06/22**

Update count: **0**

Registration date

2021-09-13, 1400/06/22

Registrant information

Name

Ahmadreza Sardarian

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3626 3193

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-10-06, 1400/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Nano hydroxyapatite_containing tooth paste on enamel demineralization during the first six months of fixed orthodontic treatment- A triple-blind randomized clinical trial

Public title

Effect of Nano hydroxyapatite_containing tooth paste on the health of the enamel during orthodontic treatment.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Need for comprehensive orthodontic treatment by fixed appliances at least in the upper arch Permanent dentition No plaque accumulation or gingival inflammation before bracket bonding Good general health

Exclusion criteria:

Patients with smoking habit Patients with tooth anomalies Patients with active dental caries

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 36

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be carried out using a computer-generated random number sequence to produce random samples. Each consecutive patient labeled by random number go through block randomization with a block length 18. The patients will be equally divided into two groups, namely, the TP1 and TP2 group. The distribution of the group to be first assigned will be recorded on sequentially numbered cards and placed in opaque and sealed envelopes. Each participant randomly picks one envelope corresponding to either the TP1 or TP2 group. Once the participant is eligible for the procedure and all initial evaluations are completed, the allocation assignment will be revealed by opening the envelope immediately after implementation.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The trial will be triple-blinded. Both the participants and clinician will be masked to group allocation and they will not be aware of the type of toothpaste. The toothpastes given to the patients will be subjected to surface treatment with an abrasive cloth to remove all information regarding its contents. That way, the patients and the clinician responsible for the treatment will be blinded to the treatment that they receive. The person who uses DIAGNOdent to measure the enamel demineralization is also unaware of how individuals are assigned to the groups. Furthermore, the individual analyzing the data will be unaware of the study protocol.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shiraz University of Medical Sciences

Street address

Orthodontics Research Center, Department of Orthodontics, Shiraz University of Medical Science, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7195615878

Approval date

2021-08-25, 1400/06/03

Ethics committee reference number

IR.SUMS.DENTAL.REC.1400.058

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

Enamel demineralization, Nano hydroxyapatite, Fixed orthodontic treatment

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

The amount of enamel demineralization is measured by

the number indicated by the DIAGNOdent device.

Timepoint

The enamel demineralization will be recorded 3 times during the first 6 months of fixed orthodontic treatment. At the start of the study and 3, 6 months during the treatment.

Method of measurement

Evaluating by DIAGNOdent device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The teeth will be etched at the bracket base area with 37% phosphoric acid for 15 seconds, rinsed, and dried. Transbond XT Adhesive Primer and Transbond XT Adhesive Resin will be used for bonding metal brackets. Bonding procedures will be performed according to the manufacturer's instructions. Stainless steel brackets will be placed and firmly pressed onto the enamel surfaces and excess adhesive will be removed from the bracket base periphery. If a slight bit of excess adhesive is present after setting (especially along the gingival margin), it will be removed with burs. Patients in the experimental group brush with Nano-hydroxyapatite toothpaste 3 times a day.

Category

Treatment - Other

2

Description

Control group: The teeth will be etched at the bracket base area with 37% phosphoric acid for 15 seconds, rinsed, and dried. Transbond XT Adhesive Primer and Transbond XT Adhesive Resin will be used for bonding metal brackets. Bonding procedures will be performed according to the manufacturer's instructions. Stainless steel brackets will be placed and firmly pressed onto the enamel surfaces and excess adhesive will be removed from the bracket base periphery. If a slight bit of excess adhesive is present after setting (especially along the gingival margin), it will be removed with burs. Patients in the control group brush with fluoride toothpaste 3 times a day.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Orthodontics, Faculty of Dentistry, Shiraz University, Shiraz, Iran

Full name of responsible person

Ahmadreza Sardarian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi Pharm.D , PhD

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Ahmadreza Sardarian

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Latest degree

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Other areas of specialty/work

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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

All patient data can be tracked through the journal site.

When the data will become available and for how long

The data will be provided to the journal and the exact time of availability of the information will be announced by the journal.

To whom data/document is available

Eligibility for access to information is determined by the relevant journal rules.

Under which criteria data/document could be used

Eligibility for access to information is determined by the relevant journal rules.

From where data/document is obtainable

All patient data can be tracked through the journal site. Therefore, by searching for articles on reputable sites, it will be possible to follow and access information.

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

All patient data can be tracked through the journal site. Therefore, by searching for articles on reputable sites, it will be possible to follow and access information.

Comments