Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

The effect of Nano hydroxyapatite containing tooth paste on tooth discoloration 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 effect of Nano hydroxyapatite tooth paste in this tooth discoloration.

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 tooth discoloration 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 laboratory technician taking the photographs will be masked to intervention. Furthermore, the individual analyzing the data will be unaware of the study protocol.

Participants/Inclusion and exclusion criteria

The inclusion criteria will be (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 will be patients with a smoking habit, tooth anomalies and active dental caries.

Intervention groups

Before treatment, patients in the experimental and control groups will be trained and informed to maintain oral hygiene with fixed appliances and to brush at least 3 times a day with Nano hydroxyapatite and white fluoride toothpaste respectively. All the patient will use toothbrush with soft bristles. Patients will not be permitted to routinely use staining mouth rinses or beverages during orthodontic treatment. 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 tooth discoloration during the first six months of fixed orthodontic treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191127045518N1**
Registration date: **2020-09-16, 1399/06/26**
Registration timing: **retrospective**

Last update: **2020-09-16, 1399/06/26**
Update count: **0**

Registration date

2020-09-16, 1399/06/26

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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sadra.sardarian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-31, 1399/06/10

Expected recruitment end date

2020-09-15, 1399/06/25

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 tooth discoloration 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 tooth discoloration 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:

smoking habit tooth anomalies 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

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 laboratory technician taking the photographs will be masked to intervention. 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

2020-04-29, 1399/02/10

Ethics committee reference number

IR.SUMS.DENTAI.REC.1399.053

Health conditions studied

1

Description of health condition studied

Tooth discoloration, Nanohydroxyapatite, Fixed Orthodontic treatment

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of patients who have a color measurement criterion (ΔE) of more than one unit

Timepoint

The tooth color 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

Digital photographic assessment

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 will be brush at least 3 times a day with Nano hydroxyapatite toothpaste.

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 will be brush at least 3 times a day with fluoride toothpaste.

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

Assisstant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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
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