

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the anti-cariogenic effect of chitosan-nano amorphous calcium phosphate and chitosan-nano hydroxyapatite varnish around orthodontic brackets; A Randomized clinical trial

Protocol summary

Study aim

The effects of 4 varnish in patients undergoing fixed orthodontic treatment

Design

Parallel group, Randomized clinical trial, Triple blind (patient, examiner and assessor), 120 patients, Using dynamic randomized block

Settings and conduct

Two weeks before bonding session all patients will attend a specialized scaling, debridement and polishing appointment and will receive standard oral hygiene instructions (tooth brushing twice a day and flossing every day). At the end of treatment, the dental arches will be isolated and dried, and then the varnish will be applied on the buccal surface surrounding the bracket using a microbrush. After about five minutes of setting time, the patient will be asked to refrain from eating or drinking for four hours and not to brush the experimental teeth for six hours. Varnish application will be done every 3 months until the end of the treatment. This will be treated in a private orthodontics office.

Participants/Inclusion and exclusion criteria

Inclusion criteria Patients aged 14-29 years old; all maxillary permanent teeth present up to at least first molars
Exclusion criteria History of any previous orthodontic treatments; history of bleaching agents or topical fluoridation within the last six months; severe crowding of >6mm or severely rotated teeth; necessitating extraction of teeth; blocked out teeth that restricts the patient's hygienic access; caries or fluorosis or hypocalcification; existence of dental crowns; amalgam or composite restorations which extended to buccal surface of teeth; any systemic or endocrine problems; craniofacial anomalies and lip or palatal clefts and smoking habits; chronic use of medication causing a dry mouth or known xerostomia; known pregnancy or breastfeeding

Intervention groups

CMC/ACP, CMC/HA, fluoride and placebo varnish.

Main outcome variables

Fluorescence and Diagnodent assessment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220219054065N1**

Registration date: **2022-02-24, 1400/12/05**

Registration timing: **prospective**

Last update: **2022-02-24, 1400/12/05**

Update count: **0**

Registration date

2022-02-24, 1400/12/05

Registrant information

Name

Shiva Torabi Ardekani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3631 0925

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-28, 1400/12/09

Expected recruitment end date

2025-02-27, 1403/12/09

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the anti-cariogenic effect of chitosan-nano amorphous calcium phosphate and chitosan-nano hydroxyapatite varnish around orthodontic brackets; A Randomized clinical trial

Public title
Evaluation of the anti-cariogenic effect of chitosan-nano amorphous calcium phosphate and chitosan-nano hydroxyapatite varnish

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 14-29 years old who require fixed orthodontic therapy All maxillary permanent teeth present up to at least first molars Good overall health Good oral hygiene (with plaque score $\leq 20\%$) No visible discontinuous band of plaque at the gingival margin of teeth and no bleeding on probing after 30 seconds Normal stimulated salivary flow rate (>1.0 mL/min) and buffer capacity (a final pH of 6.0 and 7.0)
Exclusion criteria:
History of any previous orthodontic treatments or extractions History of using any bleaching agents or topical fluoridation within the last six months Non-observance of oral hygiene instructions Sever crowding of >6 mm or severely rotated teeth , necessitating extraction of teeth Blocked out teeth and high buccal teeth that restricts the patient hygienic access also put limitation for visual and diagnostic examinations Any dental morphologic anomaly, intrinsic or extremely heavy extrinsic staining Visible signs of caries or fluorosis or hypocalcification and also any developmental defects Existence of dental crowns, amalgam or composite restorations which extended to buccal surface of teeth Any systemic or endocrine problems (such as diabetes or cardiovascular diseases), craniofacial anomalies and lip or palatal clefts and smoking habits Any WSLs present on qualified teeth with and without frank cavitation, alterations of the enamel, e.g. hypoplasia, fluorosis Chronic use of medication causing a dry mouth or known xerostomia; known pregnancy or breastfeeding during the course of the study Professional administration or home use of highly concentrated fluoride products not related to the study during the whole study

Age
From **14 years** old to **29 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyst

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
All the participants will be randomized using a dynamic randomized block design for balancing age and sex. A block randomization list will be created by <https://www.sealedenvelope.com> with a block size of eight. The group allocation will be carried out by an assistant not directly involved in the study only after each patient will be seated for the initial bonding appointment, and a random numerical code will be assigned to each patient at the beginning of the study based on the randomization list created before. Groups I, II, III and IV will include subjects using CMC/ACP, CMC/HA , fluoride and placebo varnish respectively.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The patients, therapists, and the data assessors will be blinded to the type of varnish used. In this regard, the varnish bottles' shapes will be similar and labeled as A, B and C and D randomly by a person not involved in this study.

Placebo
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
Unit9, Floor 3, Kuhsar Mahdi hwy, Ghasrodasht blv.

City
Shiraz

Province
Fars

Postal code
7195735999

Approval date
2022-02-15, 1400/11/26

Ethics committee reference number
IR.SUMS.DENTAL.REC.1400.140

Health conditions studied

1

Description of health condition studied
Dental caries

Primary outcomes

1

Description

Fluorescence assessment

Timepoint

every 3 months

Method of measurement

The teeth will be scanned carefully by the same dentist blinded as to group allocation of the subjects using probe tip B held in contact with the tooth surface and tilted around the measuring site rocking slowly in a pendulous motion so that fluorescence can be collected from all directions at 4 labial sites on the enamel (gingival, occlusal, mesial, and distal) around the brackets. The peak reading displayed on the panel of the DIAGNOdent pen during the scan will be recorded for each site of tooth surface. Then the mean of 4 sites for each tooth will be calculated and recorded. For each patient the mean scores of all 10 maxillary teeth that are included in the study will be calculated and a mean DD reading number for each patient will be recorded

Secondary outcomes

1

Description

Visual assessment of WSL (Gorelick assessment)

Timepoint

every 3 months

Method of measurement

Before applying varnish at baseline(T0) ,3 months(T1), 6 months(T2) , 9 months(T3) and 12 months (T4) and at the end of the treatment(T5) , three standardized intraoral photographs (one frontal and two laterals) will be taken by a commercial SLR camera Nikon D5300 (Nikon Corporation, Tokyo, Japan) outfitted with a 24 to 85 mm macro lens and an SB29s Macro Speedlight from patients in natural head position after cleaning and drying the teeth as mentioned above. Then, the photographs will be stored on a USB device, the cropped and color-matched before-and-after images for each patient will be imported into a Power- Point (Microsoft, Redmond, Wash) slide with a black background and the presence and severity of white spot lesions will be evaluated independently by two orthodontics specialists who are blinded with regard to the treatment group each patient belongs to. The labial surfaces of the maxillary incisors, cuspids and premolars will be assessed according to Gorelick et al.: Score 1 = no white spot formation; Score 2 = slight white spot formation (thin rim); Score 3 = excessive white spot formation (thicker bands); and Score 4 = white spot formation with cavitation.

Intervention groups

1

Description

First group : Chitosan-nano hydroxyapatite. CMC will be prepared by Hangzhou New Asia International Co.,Ltd,China). HA ($\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$, white powder , size of nano particles < 50 nm) will be prepared by Tamadkala (Tehran,Iran,Arminano brand). The varnish base will be prepared by mixing hydrogenerated rosin with absolute ethanol at a 3:1 (W/W) ratio in a closed vessel on a stirrer at room temperature for 24hours. 5% (W%) chitosan and 10 % (W%) nano-HA will be added to the varnish base (hydrogenerated rosin (50% W) with absolute ethanol (35% W)) for CMC/nano-HA varnish production. Varnish application will be done at the first session and then every 3 month until the end of the treatment.

Category

Prevention

2

Description

Second group: Chitosan-nano Amorphous calcium phosphate. CMC will be prepared by Hangzhou New Asia International Co.,Ltd,China). Nano Amorphous calcium phosphate will be prepared by Dr.Atai(Iran Polymer and Petrochemical institute. Tehran Province, Tehran). The varnish base will be prepared by mixing hydrogenerated rosin with absolute ethanol at a 3:1 (W/W) ratio in a closed vessel on a stirrer at room temperature for 24hours. 5% (W%) chitosan and 10 % (W%) nano-ACP will be added to the varnish base (hydrogenerated rosin (50% W) with absolute ethanol (35% W)) for CMC /nano-ACP varnish production. Varnish application will be done at the first session and then every 3 month until the end of the treatment.

Category

Prevention

3

Description

Third group: Fluoride Varnish. 5% Ariadent fluoride varnish will be prepared by Asia chemiTeb Co.(Tehran , Iran).

Category

Prevention

4

Description

Control group: Placebo Varnish

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Private office of Dr. Hooman Zarif Najafi
Full name of responsible person
Hooman Zarif Najafi
Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Mahtab Memarpour
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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
Hooman Zarif Najafi
Position
Associate professor
Latest degree
Specialist
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

part of data such as information about the main outcome can be shared

When the data will become available and for how long

start of access 6 months after publishing of the results

To whom data/document is available

our data will be accessible only to higher education researchers.

Under which criteria data/document could be used

if data needs authentication for further studies, writers will be accessible.

From where data/document is obtainable

for further information , please contact Shiraz University of Medical Science (SUMS) , please.

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

further questions will be responded at library.sums.ac.ir

Comments