Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 undegoing 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 month untill 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; sever crowding of >6mm or severely rotated teeth; necessitating extraction of teeth; blocked out teeth that ristricts the patient 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

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Iran (Islamic Republic of)

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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 ≤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-observence of oral hygiene instructions Sever crowding of >6mm or severely rotated teeth , necessitating extraction of teeth Blocked out teeth and high buccal teeth that ristricts the patient hygienic access also put limitation for vissual and diagnodent examinations Any dental morphologic anomaly,intrinsic or extremly 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 analyser

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

ICD-10 code
ICD-10 code description

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 Intrernational Co.,Ltd,China). HA (Ca10(Po4) 6(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 untill the end of the treatment.
Category
Prevention

2

Description
Second group: Chitosan-nano Amorphous calcium phosphate. CMC will be prepared by Hangzhou New Asia Intrernational 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 untill the end of the treatment.
Category
Prevention

3

Description
Third group: Flouride Varnish. 5% Ariadent floride 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahtab Memarpoor
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Ghom abad street, Ghasrodasht blv. dental university of Shiraz
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Dental@sums.ac.ir
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 accessbile 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