

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the antibacterial and caries prevention effects of a varnish containing combined nanohydroxyapatite and galla chinensis in fixed orthodontic patients

Protocol summary

Study aim

Evaluation of one type of varnish in preventing the formation of white spot lesions in patients under Orthodontic treatment

Design

Parallel group, Randomized clinical trial, Double-blind (patient and examiner), 72 patients, Using dynamic randomized block

Settings and conduct

On the day of treatment, the upper jaw's teeth will be dried and isolated, then varnish is applied to the buccal surface of the tooth with a micro brush, after one minute the patient is asked to spit, and this process is repeated every four weeks for 7 months. This process will be done in the orthodontics department of the dentistry school.

Participants/Inclusion and exclusion criteria

Inclusion criteria:: ١. Age range of ١٤ to ٢٩ years ٢. Absence of any systemic disease ٣. No use of antibiotics or antibacterial mouthwash in the previous month ٤. Periodontal health, absence of current caries or enamel demineralization ٥. All permanent dentition is present up to the first molar. ٦. No history of prior orthodontic or periodontal therapy. ٧. No smoking habit Exclusion criteria ١. Visible sign of dental hypo-calcification ٢. Craniofacial anomalies ٣. History of cleft lip and palate deformities ٤. History of dental restorative treatment on the buccal surface ٥. History of long term use of anti-inflammatory drugs ٦. History of glass ionomer dental restorative treatment

Intervention groups

Parallel groups, randomized clinical trial

Main outcome variables

Caries assessment, Evaluation of bacterial count

General information

Reason for update

the trial is finished

Acronym

IRCT registration information

IRCT registration number: **IRCT20220907055913N1**

Registration date: **2022-09-16, 1401/06/25**

Registration timing: **prospective**

Last update: **2025-03-01, 1403/12/11**

Update count: **1**

Registration date

2022-09-16, 1401/06/25

Registrant information

Name

Faezeh Bahraini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3626 3192

Email address

fbahraini@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-07, 1401/07/15

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

2022-10-22, 1401/07/30

Actual recruitment end date

2022-11-20, 1401/08/29

Trial completion date

2023-07-01, 1402/04/10

Scientific title

Evaluation of the antibacterial and caries prevention effects of a varnish containing combined nanohydroxyapatite and galla chinensis in fixed orthodontic patients	
Public title	Parallel
Evaluation of caries control effect of a varnish containing combined nanohydroxyapatite and galla chinensis	Other design features
Purpose	Secondary Ids
Prevention	empty
Inclusion/Exclusion criteria	Ethics committees
Inclusion criteria:	1
The age range of 14 to 29 years Absence of any systemic disease Periodontal health, absence of current caries or enamel demineralization. All permanent dentition is present up to the first molar No history of prior orthodontic or periodontal therapy No smoking habit No use of antibiotics or antibacterial mouthwash in the previous month	Ethics committee
Exclusion criteria:	Name of ethics committee
Visible sign of dental hypo-calcification Craniofacial anomalies History of cleft lip and palate deformities History of dental restorative treatment on the buccal surface History of long term use of anti-inflammatory drugs History of glass ionomer dental restorative treatment	Ethics committee of Shiraz University of Medical Sciences
Age	Street address
From 14 years old to 29 years old	Unit9, Floor 3, Kuhsar Mahdi hwy, Ghasrodasht blv.
Gender	City
Both	Shiraz
Phase	Province
3	Fars
Groups that have been masked	Postal code
- Participant - Investigator	7195735999
Sample size	Approval date
Target sample size: 72	2022-09-06, 1401/06/15
Actual sample size reached: 72	Ethics committee reference number
Randomization (investigator's opinion)	IR.SUMS.DENTAL.REC.1401.057
Randomized	Health conditions studied
Randomization description	1
To balance the age and sex variables, the randomization will be done using block randomization for all participants. https://www.sealedenvelope.com will generate a block randomization list with a 4-block size. T During the initial bonding appointment, a random code will be given to each patient based on the randomization list by an assistant who is not directly involved in the study. Groups I and II will include subjects using GCE/n-HA varnish (test) and placebo varnish (negative control) respectivel	Description of health condition studied
Blinding (investigator's opinion)	dental caries
Double blinded	ICD-10 code
Blinding description	ICD-10 code description
The patients and orthodontist will be blinded to the type of varnish used. In this regard, the varnish bottles' shapes will be similar and labeled as 1 and 2 by a person not involved in this study	Primary outcomes
Placebo	1
Used	Description
Assignment	caries assessment(florescent and visual assesment)
	Timepoint
	Initial values (T·) , 1 months(T1) , 4 months(T2) , 6 months(T3) of use of various anti-demineralizing agents
	Method of measurement
	1. Visual assessment: All measures will be taken by the same examiner, who is calibrated before the research. Before bonding, the initial visual assessment will be done. The international caries detection and assessment system II (ICDAS II) will be used to inspect and record the buccal surfaces of the test subjects' teeth at each visit. After 4 seconds of compressed air drying on the tooth surfaces, the examination will be done. The evaluation will be conducted with the use of a mouth mirror and a blunt probe under clinical illumination in accordance with the ICDAS II index criteria. The mean scores of all 1· maxillary teeth involved in the research will be computed for each patient, and a mean reading number will be recorded. 2. Florescent assessment: 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 the 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 included in the study will be calculated and a mean Diagnodent reading number for each patient will be recorded.

Secondary outcomes

1

Description

bactreal colony count

Timepoint

plaque sampling and bacterial culturing will be done at the following time intervals: Initial values (T0) ,1 months(T1), 4 months(T2) , 7 months(T3) of use of various anti-demineralizing agents

Method of measurement

On the day of the appointment, the patient will be refrained from eating or brushing their teeth. Ligatures and archwires will be carefully removed at each appointment. The collecting sites will be gently air dried after being isolated of the excess water and saliva with cotton rolls. Plaque samples will be collected using a sterile cotton swab from the labial surfaces of the considered teeth. By moving the tip of the sterile cotton swab along the occlusal, mesial, gingival, and distal edges of the bracket base, and while holding the tip in constant contact with the tooth surface adjacent to the base of bracket, dental plaque will be collected. Sterile cotton swabs will be rapidly transferred to the samples transport media (thioglycolate broth carrier medium) and to anaerobic bacteria culture media. Microbial samples will be cultivated and analyzed by the same examiner in the Department of Clinical Microbiology of Shiraz University of Medical Sciences. According to G. WESTERGREN AND B. KRASSE, the sample will be cultured.

Intervention groups

1

Description

Control group: Placebo Varnish

Category

Placebo

2

Description

Intervention group: varnish combined galla chinensis(GCE) and nano hydroxyapatite(HA). HA (Ca10(Po4) 6(OH)2 , white powder , size of nano particles

< 20 nm) will be prepared by APATECH (Yazd, Yazd Science and Technology park, Iran). The varnish base will be prepared by mixing hydrogenated rosin with absolute ethanol at a 3:1 (W/W) ratio in a closed vessel on a stirrer at room temperature for 24hours. 4000 ppm of galla chinensis and 10 % (W%) nano-HA will be added to the varnish base (hydrogenerated rosin (50% W) with absolute ethanol (35% W)) for GCE/nano-HA varnish production. Varnish application will be done at the first session and then every month until 7 month.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

orthodontic department of dentistry school of Shiraz university of medical sciences

Full name of responsible person

Shabnam Ajami

Street address

Orthodontic department, School of Dentistry, Qom Abad, Qasrodasht Ave

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Shiraz

Province

Fars

Postal code

7195615878

Phone

+98 71 3626 3193

Email

dr.ajami.sh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mahtab Memarpour

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7195615878

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Email

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
Shabnam Ajami
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Latest degree
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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 the library.sums.ac.ir

Comments