Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Treatment of post-orthodontic white spot lesions with 10% xylitol varnish: A randomized Clinical Trial

Protocol summary

Study aim
To evaluate the remineralizing effect of 10% xylitol varnish compared to 5% fluoride varnish and routine dental care on white spot lesions formed after fixed orthodontic treatment.

Design
Clinical randomized trial of 84 patients with three-arm parallel group (with 1: 1: 1 ratio) and triple-blind. Block randomization list will be created by https://www.sealedenvelope.com with a block size of six.

Settings and conduct
Private office of Dr. Hooman Zarif Najafi Clinician, patients and data analyzer will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged between 14 and 25 years old who had completed fixed orthodontic treatment recently with at least one WSL on the facial surface of eight maxillary anterior teeth. Exclusion criteria: Patients with chronic disease; Any abnormal oral, medical, or mental condition; neuropsychiatric disorders; Regular use of oral antiseptics; Any WSLs present on qualifying teeth with frank cavitation; Extensive restorations on the facial surfaces of the study teeth; Dental morphologic/ anatomical/developmental anomalies; Alterations of the enamel, e.g. hypoplasia, fluorosis; Chronic use of medication causing a dry mouth; Known pregnancy or breastfeeding; Professional administration or home use of highly concentrated fluoride productsduring the whole study.

Intervention groups
First intervention group: Xylitol 10% varnish Second intervention group: Fluoride 5 % varnish Control group: Placebo varnish

Main outcome variables
Enamel mineral content

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180913041032N2**
Registration date: **2021-12-03, 1400/09/12**
Registration timing: **prospective**

Last update: **2024-12-09, 1403/09/19**
Update count: **1**

Registration date
2021-12-03, 1400/09/12

Registrant information

Name
Mojgan Shavakhi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3625 7449

Email address
shavakhi.m@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-11, 1400/09/20

Expected recruitment end date
2022-05-10, 1401/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Treatment of post-orthodontic white spot lesions with 10% xylitol varnish: A randomized Clinical Trial

Public title
Effect of xylitol in treatment of post-orthodontic white spot lesions
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The subjects will be chosen within patients aged between 14 and 25 years old who had completed fixed appliance orthodontic therapy recently. Have at least one WSL on the facial surface of eight maxillary anterior teeth that was not presented before orthodontic treatment.
Exclusion criteria:
Patient’s unwillingness to be randomly assigned to one of the three treatment groups Ongoing medication for a chronic disease Chronic conditions such as asthma and allergy Any abnormal oral, medical, mental condition or neuropsychiatric disorders Regular use of oral antiseptics Any WSLs present on qualifying teeth with frank cavitation, Extensive restorations on the facial surfaces of the study teeth Dental morphologic, anatomical or developmental anomalies 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 **25 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
All the participants will be randomized using 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 six. The group allocation will be revealed by an assistant not directly involved in the study and a random code number will be assigned to each patient based on the randomization list created at the beginning of study.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The participating patients, the main therapist corresponding the varnish administration and evaluate the study outcome, the person who collect and analyses data and the persons prepares the results report will be blinded with respect to the type of varnish used. In this regard the placebo varnish will be specially manufactured by the Asia ChemiTeb Co with the same basic composition and viscosity as the commercial Ariadent fluoride varnish (Asia ChemiTeb Co., Tehran, Iran). All varnishes will be stored in similar tubes and will be labeled as A, B and C.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Dentistry-Shiraz University of Medical Sciences
Street address
School of Dentistry, Qom Abad, Ghasrodasht St
City
Shiraz
Province
Fars
Postal code
713451836
Approval date
2021-07-14, 1400/04/23
Ethics committee reference number
IR.SUMS.DENTAL.REC.1400.048

Health conditions studied

1

Description of health condition studied
White spot lesions
ICD-10 code
K02.61
ICD-10 code description
Dental caries on smooth surface limited to enamel

Primary outcomes

1

Description
Enamel mineral content
Timepoint
Baseline, 6 and 12 month post orthodontic treatment
Method of measurement
DIAGNOdent pen

Secondary outcomes

1

Description
visual assessment of white spot lesions
Timepoint
baseline and 12 month post orthodontic treatment
Method of measurement
The labial surface of maxillary incisors, cuspids and premolars will be assessed according to Gorlick et al. score 1: no white spot lesion, score 2: slight white spot lesion (thin rim). score 3: excessive white spot lesion (thick band), and score 4: white spot lesion with cavitation.

Intervention groups

1

Description
Intervention1: 5% fluoride varnish: Ariadent fluoride varnish (Asia ChemiTeb Co, Tehran, Iran). At the time of debonding, remaining composite material on the enamel surfaces will be removed with 12-bladed tungsten carbide bur and a low-speed hand piece followed by polishing with a rubber cup a fluoride-free pumice paste . The varnish will be applied with a small brush in a thin layer of the facial surface of the eight anterior maxillary teeth. After 60 s of setting, the patients will be instructed not to drink within 60 min, not to eat for 4 h, and brush their teeth until the next day morning. This process will be repeated every three months (4 times during study) after cleaning and drying the teeth.
Category
Treatment - Drugs

2

Description
Intervention 2: 10% xylitol varnish. Xylitol varnish will be especially manufactured by Asia ChemiTeb Co (Tehran, Iran) with the same basic composition as the commercial Ariadent fluoride varnish (Asia ChemiTeb Co, Tehran, Iran). At the time of debonding, remaining composite material on the enamel surfaces will be removed with 12-bladed tungsten carbide bur and a low-speed hand piece followed by polishing with a rubber cup a fluoride-free pumice paste . The varnish will be applied with a small brush in a thin layer of the facial surface of the eight anterior maxillary teeth. After 60 s of setting, the patients will be instructed not to drink within 60 min, not to eat for 4 h, and brush their teeth until the next day morning. This process will be repeated every three months (4 times during study) after cleaning and drying the teeth.
Category
Treatment - Drugs

3

Description
Control group: Placebo varnish, placebo varnish will be especially manufactured by Asia ChemiTeb Co (Tehran, Iran) with the same basic composition as the commercial Ariadent fluoride varnish (Asia ChemiTeb Co, Tehran, Iran). At the time of debonding, remaining composite material on the enamel surfaces will be removed with 12-bladed tungsten carbide bur and a low-speed hand piece followed by polishing with a rubber cup a fluoride-free pumice paste . The varnish will be applied with a small brush in a thin layer of the facial surface of the eight anterior maxillary teeth. After 60 s of setting, the patients will be instructed not to drink within 60 min, not to eat for 4 h, and brush their teeth until the next day morning. This process will be repeated every three months (4 times during study) after cleaning and drying the teeth.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Hooman Zarif Najafi private office
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Vice Chancellor for Research and Technology: Dr. Mahtab Memarpoor
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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

Dentistry

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Mojgan Shavakhi

Position

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Latest degree

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data of primary and secondary outcomes are possible to be shared.

When the data will become available and for how long

The date of accessibility will be from the results publication.

To whom data/document is available

For whom interested

Under which criteria data/document could be used

No specific condition needed

From where data/document is obtainable

For receiving the documents, contact the following E-mail address: shavakhi.m@gmail.com

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

The request of getting the documents should be sent through an official email. The email contents include the name and position of the person receiving the data and the reason of requesting. After evaluation by corresponding author, the documents file will be sent within 1 to 2 weeks.

Comments