

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 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 products during 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

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Province

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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

Hooman Zarif Najafi

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zarifhooman@gmail.com

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 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

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mojgan Shavakhi

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Latest degree

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Person responsible for updating data

Contact

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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

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