

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation the Preventive Effect of Two Concentration of Xylitol Varnish vs Fluoride Varnish on Enamel Demineralization Around Orthodontic Brackets: A randomized controlled trial

Protocol summary

Study aim

Comparing the anti-demineralization effect of different concentration of xylitol varnish with fluoride varnish and placebo varnish around the orthodontic brackets.

Design

Single center, double blind, four-arm parallel groups, placebo- and active randomized trials, with 1: 1: 1: 1 ratio. Each group consists of 30 patients. Two groups will receive the experimental materials and two groups will serve as positive and negative controls (fluoride serves as positive control and placebo as negative control).

Settings and conduct

The subjects will be chosen within patients aged between 13 and 17 years requiring fixed orthodontic treatment at Emam Reza dental clinic. The patients, therapist and the data collector and analyzer will be blinded with respect to the type of varnish used. In this regard the varnish tubes will be labeled as A, B, C and D.

Participants/Inclusion and exclusion criteria

The inclusion criteria will be: Patients with Class I malocclusion and complete permanent dentition up to the first molars, good overall health and good oral hygiene, normal salivary flow rate and buffer capacity. Patients will be also excluded if they have history of previous orthodontic treatment or extractions, bleaching or topical fluoridation, severe crowding >6 mm, severely rotated teeth, Visible sign of caries, fluorosis, hypocalcification or developmental defects, dental filling which extended to the buccal surface, systemic or endocrine condition, craniofacial anomalies and clefts, and if they are smokers.

Intervention groups

1. 10 % Xylitol varnish 2. 20% xylitol varnish 3. Ariadent sodium fluoride varnish 5% manufactured by Asia Chemi Teb Co 4. Placebo varnish Xylitol and placebo varnishes will be specially manufactured by Asia Chemi Teb Co with the same basic composition as the commercial

Ariadent fluoride varnish.

Main outcome variables

Diagnodent number

General information

Reason for update

Reviewer requests of an orthodontics journal to continue the study until the end of orthodontic treatment and to add secondary outcomes.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180913041032N1**

Registration date: **2018-10-14, 1397/07/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-30, 1399/10/10**

Update count: **1**

Registration date

2018-10-14, 1397/07/22

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

2018-09-13, 1397/06/22

Expected recruitment end date

2018-12-11, 1397/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the Preventive Effect of Two Concentration of Xylitol Varnish vs Fluoride Varnish on Enamel Demineralization Around Orthodontic Brackets: A randomized controlled trial

Public title

Effect of Xylitol Varnish in Caries Prevention Around Orthodontic Brackets

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Class I malocclusion and complete permanent dentition up to the first molars. Good overall health and good oral hygiene (full mouth plaque score < 20 %); with no bleeding after 30 seconds or having a discontinuous band of plaque at the gingival margin. Normal salivary flow rate (>1.0 mL/min) and buffer capacity (final pH between 6.0 and 7.0).

Exclusion criteria:

History of previous orthodontic treatment or extractions, bleaching or topical fluoridation. Severe crowding >6 mm, severely rotated teeth. Visible sign of caries, fluorosis, hypocalcification or developmental defects. Dental crowns, amalgam or composite filling which extended to the buccal surface. Systemic or endocrine condition (such as cardiac pacemakers or diabetes mellitus). Craniofacial anomalies and clefts Smokers.

Age

From **13 years** old to **17 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Dynamic randomized block design for balancing age and sex with block size of 8 using online randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients, therapist and the data collector and analyzer will be blinded with respect to the type of varnish used. In this regard the varnish tubes will be

labeled as A, B, C and D.

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

School of Dentistry, Ghasr o Dasht St

City

shiraz

Province

Fars

Postal code

7195615878

Approval date

2018-09-12, 1397/06/21

Ethics committee reference number

IR.SUMS.REC.1397.413

Health conditions studied

1

Description of health condition studied

Demineralization around Orthodontic brackets.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mean Diagnodent number

Timepoint

Before starting intervention, 3 and 6 months later and at the end of orthodontic treatment.

Method of measurement

Diagnodent pen 2190

Secondary outcomes

1

Description

Visual assessment of white spot lesions.

Timepoint

At the end of orthodontic treatment.

Method of measurement

With the Gorelick index.

2**Description**

Assessment of patients satisfaction of varnish therapy.

Timepoint

After varnish therapy for patient

Method of measurement

Satisfaction questionnaire with binary (Yes/No) design.

Intervention groups**1****Description**

Intervention group 1: Xylitol varnish 10%

Category

Treatment - Drugs

2**Description**

Intervention group 2: Xylitol varnish 20 %

Category

Treatment - Drugs

3**Description**

Intervention group 3: Sodium fluoride varnish 5%

Category

Treatment - Drugs

4**Description**

Control group: Placebo varnish

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Clinic of Emam Reza

Full name of responsible person

Mojgan Shavakhi

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Namazi Sq

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Shabnam Ajami

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Vice President of Research, School of Dentistry, Ghasr o Dasht St

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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

Mojgan Shavakhi

Position

Resident of Orthodontics

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hooman Zarif Najafi
Position
Associate professor
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

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