

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of combination of xylitol and fluoride varnish on microbial biofilm and saliva in fixed orthodontic patients: a randomized clinical trial

Protocol summary

Study aim

Evaluation of effect of combination of Xylitol and Fluoride on Streptococcus mutans and lactobacillus around orthodontic brackets

Design

Clinical trial with control group, with parallel groups, three-way blind, randomized, randomization with using software

Settings and conduct

120 participants will be recruited from orthodontic patients attending the orthodontic clinic at the Dental Faculty of Shiraz University of Medical Science. Before the intervention, saliva sample and biofilm sample from around the patient orthodontic bracket will be taken, then varnish will be applied to all maxillary and mandibular teeth. The patients will be requested not to eat or drink for 2 hours and not to brush their teeth until the next day. The varnish procedure will be repeated after 1 month. Then, after 2 weeks, saliva sample and biofilm sample from around the patient orthodontic bracket will be taken again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male and female subjects Age between 12 and 30 years old Permanent dentition Good general health No anti-inflammatory or antibiotic medications taken in the month before the study No chewing gum or mouthwash use in the last week and during the study Brushing twice daily with fluoride toothpaste No active or untreated caries lesions or gingival inflammation
exclusion criteria : Treatment with antibiotics, steroids or any medication known to cause dry mouth in the last 3 months Poor oral hygiene Active periodontal disease Sever crowding of anterior teeth that would be likely to interfere with cleaning of tooth surface Smoking History of mouth breathing

Intervention groups

1- Fluoride group: dental varnish with 5% NaF 2- Xylitol group: dental varnish with 10% xylitol 3- Combination group: dental varnish contained 5% NaF+10% xylitol 4-

Control group: placebo

Main outcome variables

Number of Streptococcus mutans and Lactobacillus bacteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181121041713N4**

Registration date: **2021-10-12, 1400/07/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-12, 1400/07/20**

Update count: **0**

Registration date

2021-10-12, 1400/07/20

Registrant information

Name

neda babanouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3628 0801

Email address

babanouri@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-11, 1400/07/19

Expected recruitment end date

2021-11-15, 1400/08/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combination of xylitol and fluoride varnish on microbial biofilm and saliva in fixed orthodontic patients: a randomized clinical trial

Public title

Effect of fluoride and xylitol varnish on oral microorganism

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 12 and 30 years old Permanent dentition Good general health No anti-inflammatory or antibiotic medications taken in the month before the study No chewing gum or mouthwash use in the last week and during the study Brushing twice daily with fluoride toothpaste No active or untreated caries lesions or gingival inflammation

Exclusion criteria:

Treatment with antibiotics, steroids or any medication known to cause dry mouth in the last 3 months Poor oral hygiene Active periodontal disease Sever crowding of anterior teeth that would be likely to interfere with cleaning of tooth surface Smoking History of mouth breathing

Age

From **12 years** old to **30 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

Block randomization method will be used with block size of 8, using online software (RANDOM.ORG) to allocate patients to four experimental groups with a 1:1:1:1 ratio. Following the random sequence generation, random numbers will be allocated to each patient in sealed opaque envelopes. Before the varnish application, the envelope will be opened to disclose the assigned treatment.

Blinding (investigator's opinion)

Triple blinded

Blinding description

All varnishes will be spilled into identical tubes that will be color coded by the first investigator, so the clinician who assigns the intervention, the patients, laboratory

technician, and the statistician will be all blind to the treatment groups.

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

Qasrodasht Ave, Mehr Blvd

City

Shiraz

Province

Fars

Postal code

7195615878

Approval date

2021-07-14, 1400/04/23

Ethics committee reference number

IR.SUMS.DENTAL.REC.1400.036

Health conditions studied**1****Description of health condition studied**

Cariogenic bacteria in the oral cavity

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Number of bacterial colonies

Timepoint

Before beginning the intervention and 45 days later

Method of measurement

Counting the number of bacterial colonies

Secondary outcomes**1****Description****Timepoint****Method of measurement**

Intervention groups

1

Description

Intervention group: first/fluoride varnish/sodium fluoride 5 percentage(Product of Asia Chemi Teb Pharmaceutical Company) / two drops of varnish/fluoride varnish is applied to the teeth at the beginning of intervention and 30 days later.

Category

Prevention

2

Description

Intervention group: second/xylitol varnish/xylitol 10 percentage(Product of Asia Chemi Teb Pharmaceutical Company)/two drops of varnish/xylitol varnish is applied to the teeth at the beginning of intervention and 30 days later.

Category

Prevention

3

Description

Intervention group: third/combination of xylitol varnish and fluoride varnish /xylitol 10 percentage+ fluoride 5 percentage(Product of Asia Chemi Teb Pharmaceutical Company)/two drops of varnish/xylitol varnish is applied to the teeth at the beginning of intervention and 30 days later.

Category

Prevention

4

Description

Control group: placebo varnish/ simple varnish with out fluoride and xylitol (Product of Asia Chemi Teb Pharmaceutical Company)/two drops of varnish/ varnish is applied to the teeth at the beginning of intervention and 30 days later.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz school of detistry

Full name of responsible person

Neda Babanouri

Street address

Qasrodasht Ave , Mehr Blvd

City

Shiraz

Province

Fars

Postal code

7195615878

Phone

+98 71 3626 3193

Email

nedababanouri@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaian Zadeh

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71345-1978

Phone

+98 71 3626 3193

Email

rezaiana@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

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

Dr.Neda Babanouri

Position

Assistance Professor of Orthodontics, Shiraz Dental School

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Qasrodasht Ave , Mehr Blvd

City

Shiraz

Province

Fars

Postal code

7195616878

Phone

+98 71 3628 0801

Email

nedababanouri@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Neda Babanouri

Position

Assistant Professor of Orthodontics, Shiraz Dental School

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Qasrodasht Ave, Mehr Blvd

City

Shiraz

Province

Fars

Postal code

7195615878

Phone

+98 71 3628 0801

Email

babanouri@sums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Neda Babanouri

Position

Assistant Professor of Orthodontics, Shiraz Dental School

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Qasrodasht Ave, Mehr Blvd

City

Shiraz

Province

Fars

Postal code

7195615878

Phone

+98 71 3628 0801

Email

babanouri@sums.ac.ir

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