Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Streptococcusmutans 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 Streptoccus 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 varnishs 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
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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
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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

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Person responsible for updating data

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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