Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The antimicrobial efficacy of combination of chlorhexidine and nano-silver fluoride mouthwashes on Streptococcus mutans in orthodontic patients (Randomized clinical trial)

Protocol summary

Study aim

The aim of this study is to evaluate the antimicrobial efficacy of using the combination of chlorhexidine and nano-silver fluoride mouthwashes for 14 days on Streptococcus mutans in patients undergoing orthodontic therapy

Design

Clinical trial, with parallel groups, double-blind, randomized, phase 1on 45 patients. Excel software rand function is used for randomization.

Settings and conduct

This randomized double-blind study is designed to evaluate the efficacy of 3 mouthwashes and will be performed in 14 days in the orthodontic department of Tabriz Dental School. From the patients who refer to the orthodontic department, 45 people who meet the inclusion criteria will be selected and will be asked to fill out the written consent form. Patients will use 10 ml of mouthwash 2 times a day. They should wait 30 minutes to eat or drink. Saliva samples will be collected in sterile containers two times with one week interval. Mouthwashes will be poured into similar plastic containers.The patient and the researcher will not be aware of the type of mouthwash.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients not receiving antibiotic therapy for the past three weeks Patients not receiving fluoride therapy for the past three weeks patients agreed with the informed written consent previous to the study Patients in the 20-40 age range Exclusion criteria: Patients with dental prostheses (crown and bridge) Patients with soft tissue pathology Patients with poor oral health (DMFT> 8) Smokers Patients with orthodontic removable appliances

Intervention groups

Group 1(n=15): Chlorhexidine mouthwash 0.2% Group 2 (n=15): Silver fluoride nanoparticles mouthwash 0.04%

Group 3 (n=15): Mouthwash containing a mixture of 0.1% chlorhexidine and silver fluoride nanoparticles (400 ppm)

Main outcome variables

Time, amount of bacteria, Study groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210620051635N1**
Registration date: **2021-07-30, 1400/05/08**
Registration timing: **retrospective**

Last update: **2021-07-30, 1400/05/08**
Update count: **0**

Registration date

2021-07-30, 1400/05/08

Registrant information

Name

Yasaman Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 2244 5321

Email address

yasamanazizi97@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-21, 1400/03/31

Expected recruitment end date

2021-07-05, 1400/04/14

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The antimicrobial efficacy of combination of chlorhexidine and nano-silver fluoride mouthwashes on Streptococcus mutans in orthodontic patients (Randomized clinical trial)

Public title
Antimicrobial efficacy of combination of chlorhexidine and nano-silver fluoride mouthwashes on orthodontic patients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients not receiving antibiotic therapy for the past three weeks Patients not receiving fluoride therapy for the past three weeks patients agreed with the informed written consent previous to the study Patients in the 20-40 age range
Exclusion criteria:
Patients with dental prostheses (crown and bridge) Patients with soft tissue pathology Patients with poor oral health (DMFT> 8) Smokers Patients with orthodontic removable appliances
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to assign patients to the study groups, permuted block randomization method was used with three patients in each block.The created list is as follows: ACB ABC BAC ABC BCA BAC CAB BCA CAB ACB ABC CBA CAB CBA ACB The results will be reported by mean ± standard deviation and frequency percentage. Shapiro-Wilk test will be used to analyze the normality of the data. In order to compare the amount of bacteria in the study groups, analysis of variance of covariance will be used. A probability of less than 5% will be considered a significant level. For data analysis, SPSS software version 20 will be used.
Blinding (investigator's opinion)
Double blinded
Blinding description
This double-blind study is a randomized clinical study designed to evaluate the effectiveness of 3 mouthwashes and will be performed during 14 days in the orthodontic department of Tabriz Dental School. From the patients who refer to the orthodontic department, 45 people who meet the inclusion criteria will be selected and they will be asked to fill out the written consent form. Random allocation software will be used for randomization and allocation. Each eligible patient will be assigned to one of the three study groups, based on the list kept by the head of the faculty. Patients will receive their mouthwashes according to the letters of each block: A: Chlorhexidine B:Silver fluoride nano-particles C: Combined nano-silver fluoride and Chlorhexidine mouthwash ACB ABC BAC ABC BCA BAC CAB BCA CAB ACB ABC CBA CAB CBA ACB Patients will be randomly assigned to three groups. Group 1 (n = 15): Chlorhexidine mouthwash 0.2% Group 2 (n = 15): Silver fluoride nano-particles mouthwash 0.04% Group 3 (n = 15): Mouthwash containing a mixture of 0.1% chlorhexidine and silver fluoride nano-particles (400 ppm) For this purpose, mouthwash will be poured into similar plastic containers with the same size. The patient and the researcher will not be aware of the type of mouthwash.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
no10، narges alley، baghe esmail agha ave، tohid blvd
City
mahabad
Province
West Azarbaijan
Postal code
5915935945
Approval date
2021-05-22, 1400/03/01
Ethics committee reference number
IR.TBZMED.REC.1400.169

Health conditions studied

1

Description of health condition studied
dental caries in orthodontic patients
ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Time،The amount of bacteria،Studied groups
Timepoint
Before intervention - 14 days after the intervention (Using Mouthwash)
Method of measurement
Time: 2 times (before and after using mouthwash (first day and 14th)) Bacterial content: Colony counting unit study groups: Chlorhexidine, silver fluoride, combination of Chlorhexidine and silver fluoride

Secondary outcomes

1

Description
Time, The amount of bacteria, Study groups
Timepoint
2 times (before intervention and 14 days after intervention)
Method of measurement
Time: 2 times (before intervention _ 14 days after intervention) Bacterial content: colony-forming unit Study groups: 2 times (before intervention _14 days after intervention)

Intervention groups

1

Description
The first group (n = 15): Chlorhexidine mouthwash 0.2% , The second group (n = 15): Silver fluoride mouthwash 0.04% ,The third group (n = 15): Mouthwash containing 0.1% chlorhexidine mixture and silver fluoride nanoparticles (400 ppm) All patients will be asked to brush their teeth with regular toothpaste twice a day for 2-4 minutes and to rinse their mouth with 10 ml of mouthwash twice a day for 30 seconds and not to eat or drink anything for half an hour after that.The best time to use mouthwashes is before bed and after brushing.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Orthodontics , Faculty of Dentistry, Tabriz University of Medical Sciences
Full name of responsible person
amir hooman sadr haghighi
Street address
No.10 ،Third narges alley ،tohid Ave ، baghe esmail agha Blvd،mahabad, Iran
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5915935945
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Email
yasamanazizi97@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
mojgan kachoei
Street address
Faculty of Dentistry, Tabriz University of Medical Sciences
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Tabriz
Province
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Email
yasamanazizi97@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
amir hooman sadr haghighi
Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Yasaman Azizi

Position

Dentistry student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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No.10, narges 3 alley, tohid ave, baghe esmail agha blvd, mahabad city

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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

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

Title and more details about the data/document

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

researchers of academic and scientific institutions

Under which criteria data/document could be used

From where data/document is obtainable

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

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Comments