

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 1 on 45 patients. Excel software randomization 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

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Iran (Islamic Republic of)

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+98 44 2244 5321

Email address

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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

AgeFrom **20 years** old to **40 years** old**Gender**

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget 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 $\pm$ 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

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no10, narges alley, baghe esmail agha ave, tohid blvd

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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 haghghi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

mojgan kachoei

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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

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 haghghi

Position

Assistant Professor
Latest degree
Specialist
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Person responsible for updating data

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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

Comments