Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The antimicrobial efficacy of combination of chlorhexidine and triphala mouthwashes on Streptococcus mutans in orthodontic patients (Randomized clinical trial)

Protocol summary

Study aim
Antimicrobial efficacy of combination of chlorhexidine and Triphala mouthwashes on orthodontic patients

Design
Clinical trial, with parallel groups, double-blind, randomized, phase 2 on 54 patients. Excel software rand function will be used for randomization.

Settings and conduct
This double-blind study is a randomized clinical study designed to evaluate the effectiveness of 3 types of mouthwash and will be performed during 14 days in the orthodontic department of Tabriz Dental School. From the patients who refer to the orthodontic department, 54 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: Triphala C: Combined Triphala and Chlorhexidine mouthwash. for example ACB ABC BAC ABC..... Patients will be randomly assigned to three groups. For this purpose, mouthwash will be poured into similar plastic containers of the same size. The patient and the researcher will not be aware of the type of mouthwash.

Participants/Inclusion and exclusion criteria
Patients in the 20-60 age range; patients agreed with the informed written consent previous to the study; patients with fixed orthodontics; Do not have systemic diseases.

Intervention groups
Group 1 (n = 18): Chlorhexidine mouthwash 0.2% Group 2 (n = 18):Triphala 0.06% Group 3 (n = 18): Mouthwash containing a mixture of 0.1% chlorhexidine and Triphala 0.06%

Main outcome variables
Time; The number of bacteria; Studied groups

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210802052055N1**
Registration date: **2021-09-22, 1400/06/31**
Registration timing: **retrospective**

Last update: **2021-09-22, 1400/06/31**
Update count: **0**

Registration date
2021-09-22, 1400/06/31

Registrant information

Name
Iran Karimzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 4244 5322

Email address
baran.m2025@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-07, 1400/05/16

Expected recruitment end date
2021-08-21, 1400/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

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

Public title
Antimicrobial efficacy of combination of chlorhexidine and Triphala mouthwashes on orthodontic patients

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients in the 20-60 age range patients agreed with the informed written consent previous to the study patients with fixed orthodontics Do not have systemic diseases
Exclusion criteria:
Patients with dental prostheses (crown and bridge) Patients with soft tissue pathology Patients with poor oral health (DMFT> 8) Smokers periodentitis Pregnancy and Breastfeeding

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to assign patients to the study groups, permuted block randomization method will be used with three patients in each block. The sample of the created list is as follows: BCA BAC CAB BCA CAB ..... From the patients who refer to the orthodontic department, we select 54 people who meet the admission criteria and provide them with the consent form to complete. Random allocation software was used for randomization and allocation.Each eligible patient is assigned to one of the three study groups, based on the list provided to the head of the faculty. Patients receive their mouthwash according to the letters of each block: A): Chlorhexidine: B triphala C Composite triphala and Chlorhexidine Mouthwash) Patients will be randomly assigned to three groups. Group 1 (n = 18): Chlorhexidine mouthwash 0.2% Group 2 (18 people): Trifala mouthwash Group 3 (n = 18): Mouthwash containing a mixture of 0.1% chlorhexidine and Trifala For this purpose, mouthwash will be poured into similar plastic containers of the same size. The patient and the researcher will not be aware of the type of mouthwash.

Blinding (investigator's opinion)
Double blinded

Blinding description
Mouthwash will be poured into similar plastic containers of the same size and the letters A, B, C will be written on them by the secretary of the department and will be delivered to the patients according to the randomized list. The patients 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
2021-08-02, 1400/05/11

Ethics committee reference number
IR.TBZMED.REC.1400.407

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
Bacterial content

Timepoint
Before intervention - 14 days after the intervention (Using Mouthwash)

Method of measurement
Colony counting unit (The number of colonies formed is counted by CFU method)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first group (n = 18): Chlorhexidine mouthwash 0.2% 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

2

Description
Intervention group: The second group (n = 18): triphala0.06% 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

3

Description
Intervention group: The third group (n = 18): Mouthwash containing 0.1% chlorhexidine mixture and triphala 0.06% 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Tabriz University of Medical Sciences

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

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