Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

The Effect of Aloe Vera-Tea tree Mouthwash Compared with Chlorhexidine on Gingivitis Reduction in Orthodontic Patients: A Randomized Clinical Trial

Protocol summary

Study aim

Comparison of the anti-inflammatory and anti-plaque effects of 0.2% chlorhexidine and Aloe vera–tea tree combination mouthwashes on gingival (GI), sulcus bleeding (SBI), and plaque (PI) indices in fixed orthodontic patients.

Design

A parallel-group, double-blind, randomized controlled clinical trial on 60 patients. Randomization is performed using six-block randomization.

Settings and conduct

Departments of Orthodontics and Periodontics at the School of Dentistry, Mashhad University of Medical Sciences. A convenience sample of fixed orthodontic patients will be recruited during their routine visits. Two parallel groups: intervention group (Aloe vera-Tea tree mouthwash) and control group (0.2% chlorhexidine mouthwash). double-blind: Assessors _ Data Analyst

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Presence of full fixed orthodontic appliances Presence of at least 20 natural teeth in the oral cavity Moderate baseline Gingival Index (mean GI ≥ 1.0) Provision of written informed consent (and parental consent for participants under 18 years of age) Exclusion Criteria: Presence of systemic diseases Advanced periodontal disease Pregnancy or lactation History of hypersensitivity/allergy to chlorhexidine, tea tree oil, or aloe vera Smoking or hookah (waterpipe) use Use of antibiotics or anti-inflammatory drugs within the past month, or requiring antibiotic prophylaxis Systemic conditions affecting periodontal health (e.g., uncontrolled diabetes, leukemia) Regular use of other mouthwashes in the past month Non-compliance with study protocols and instructions

Intervention groups

Control group: 0.2% chlorhexidine mouthwash Intervention group: Combined Aloe vera–tea tree mouthwash

Main outcome variables

Reduction of microbial and dental plaque accumulation; Reduction of gingival inflammation and Gingival Index (GI); Reduction of Sulcus Bleeding Index (SBI).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260620069891N1**
Registration date: **2026-08-31, 1405/06/09**
Registration timing: **prospective**

Last update: **2026-08-31, 1405/06/09**
Update count: **0**

Registration date

2026-08-31, 1405/06/09

Registrant information

Name
Sina Ghasempour
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-22, 1405/09/01

Expected recruitment end date

2027-05-21, 1406/02/31

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

Scientific title
The Effect of Aloe Vera-Tea tree Mouthwash Compared with Chlorhexidine on Gingivitis Reduction in Orthodontic Patients: A Randomized Clinical Trial

Public title
Comparing Aloe Vera-Tea Tree Herbal Mouthwash with Chlorhexidine on Reducing Gum Inflammation in Orthodontic Patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Presence of full fixed orthodontic appliances Presence of at least 20 natural teeth in the oral cavity Moderate baseline Gingival Index (mean GI ≥ 1.0) Informed consent (and parental consent for participants under 18 years of age)
Exclusion criteria:
Presence of systemic diseases Advanced periodontal disease Pregnancy or lactation History of hypersensitivity/allergy to chlorhexidine, tea tree oil, or aloe vera Smoking or hookah (waterpipe) use Use of antibiotics or anti-inflammatory drugs within the past month, or requiring antibiotic prophylaxis Systemic conditions affecting periodontal health (e.g., uncontrolled diabetes, leukemia) Regular use of other mouthwashes/mouthrinses in the past month Non-compliance with study protocols and instructions
Age
From **15 years** old to **35 years** old
Gender
Both

Phase
0
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
1. Randomization Method In this study, balanced permuted block randomization with a block size of six is used to allocate participants into intervention and control groups. 2. Unit of Randomization The unit of randomization is individual. 3. Stratification No stratification is applied in the randomization process. 4. Randomization Tools Sequence Generation Instrument: Statistical software is utilized to generate the block random sequence. Allocation Concealment Instrument: Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE), impermeable to light, are utilized. 5. Random Sequence Generation The random sequence is generated prior to the start of sampling by an independent researcher/statistician who has no role in clinical examinations, data collection, or patient treatment. Given the total sample size of 60 participants and a block size of six, 10 blocks of six are calibrated. Within each 6-element block, three codes for the intervention group (A) and three codes for the control group (B) are randomly arranged in various combinations to maintain a 1:1 allocation ratio throughout the study. 6. Allocation Concealment and Blinding To implement allocation concealment and prevent bias among the investigator and participants regarding the upcoming group allocation: Allocation codes generated by the independent researcher are placed inside sealed, light-impermeable, opaque envelopes marked sequentially with serial numbers from 1 to 60. The envelopes remain strictly sealed until participant enrollment. Only after comprehensive participant evaluation, verification of inclusion and exclusion criteria, and obtaining written informed consent, the envelope corresponding to the entry sequence is opened to assign the specific mouthwash. Due to the double-blind nature of the study, the mouthwash containers are made identical in appearance, volume, color, and packaging, labeled solely with codes A and B. Consequently, outcome assessors (clinical index examiners), and the data analyst remain blinded to the assigned interventions until the completion of data analysis.
Blinding (investigator's opinion)
Double blinded
Blinding description
To achieve effective blinding, an independent individual outside the research team packages both mouthwashes (0.2% Chlorhexidine and the Aloe Vera-Tea Tree combination) in identical, unlabelled bottles that carry only randomized identification codes. An independent researcher generates the random sequence and places allocation details in sealed opaque envelopes. The breakdown of blinding for all involved parties is as follows: 1. Principal Investigator and Healthcare Personnel (Dentists and Clinical staff): The principal investigator and the clinical personnel responsible for patient care—including baseline scaling, root planing, and oral hygiene instruction—are kept unaware of the treatment group assignments. Because an independent third party handles the distribution of the coded bottles, the clinical staff cannot influence patient management based on treatment status. 2. Data Collectors and Outcome Assessors: The clinical evaluator who measures outcome variables—specifically the Gingival Index (GI), Plaque Index (PI), Sulcus Bleeding Index (SBI), and Lobene Stain Index—is completely blinded to patient group allocation. Examinations and data entry proceed strictly without any knowledge of the mouthwash type used by the participant. 3. Data Analyst and Manuscript Drafters: The biostatistician receives and analyzes the dataset using anonymized group codes (e.g., Group A and Group B). Similarly, the authors drafting the manuscript remain blinded to the true identity of the study groups until all statistical analyses are finalized and the dataset is unblinded. 4. Data Safety and

Monitoring Board (DSMB): If the safety monitoring committee reviews any adverse events or interim data, the information is provided strictly in a coded format to ensure an unbiased safety evaluation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Ghoreyshi Building, Daneshgah Street

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Postal code
9177899191

Approval date
2026-05-02, 1405/02/12

Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1405.025

Health conditions studied

1

Description of health condition studied
Gingivitis

ICD-10 code
K05.1

ICD-10 code description
Chronic gingivitis

Primary outcomes

1

Description
Gingivitis

Timepoint
Baseline: Before the start of the intervention (after initial scaling and hygiene instruction) – First assessment: 2 weeks after mouthwash use – Second assessment: 4 weeks after mouthwash use.

Method of measurement
Gingival Index (GI): Measurement and assessment of the severity of gingival inflammation (the primary tool for determining sample size and evaluating gingivitis). Sulcus Bleeding Index (SBI): Evaluated and recorded based on the method developed by Mühlemann and Son.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Aloe vera-Tea tree mouthwash

Category
Treatment - Drugs

2

Description
Control group: 0.2% chlorhexidine mouthwash

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental School of Mashhad university of medical sciences

Full name of responsible person
Sina Ghasempour

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Faculty of Dentistry, Mashhad University of Medical Sciences, Vakil Abad Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Mashhad 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
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Position
student
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available