Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigation of antimicrobial effect of green tea and chlorhexidine mouthwashes on the frequency of Streptococcus mutans strains in children with removable orthodontic appliances: a randomized clinical trial study

Protocol summary

Study aim

Determining the antimicrobial effect of green tea and 0.2% chlorhexidine mouthwashes on the frequency of Streptococcus mutans strains in children with removable orthodontic appliances.

Design

A randomized triple blind phase 3 clinical trial ,with the control group, block randomized parallel groups on 45 patients

Settings and conduct

Sampling is done from children referred to the orthodontic clinic of Kurdistan University of Medical Sciences. One group of participants receives chlorhexidine mouthwash 0.2% and another group receives green tea mouthwash. The control group receives deionized water. The participants under the intervention rinse the mouthwash for 15 days and twice a day with a volume of 5 ml and for 30 seconds. Saliva sampling from three groups of participants in the study is done in two stages, before and after using mouthwash. The samples are cultured and the colony count of the samples is done and the obtained data are evaluated and compared.

Participants/Inclusion and exclusion criteria

In this study, children who have used their appliance for more than a month and their cooperation in using the appliance has been favorable are included in the study. Children with allergies to mouthwash, systemic disease and a history of radiotherapy are prohibited from entering the study. Participating children must have a good health status and children with rampant caries and gum diseases and dental and oral infections are not included in the study.

Intervention groups

The entry of participants into each group is random using the block method. Participants are divided into three groups A, B and C: two groups with clinical intervention(recipient of treatment) and one group as control(recipient of distilled water).

Main outcome variables

Streptococcus mutans colony count

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240221061066N1**
Registration date: **2024-05-26, 1403/03/06**
Registration timing: **prospective**

Last update: **2024-05-26, 1403/03/06**
Update count: **0**

Registration date

2024-05-26, 1403/03/06

Registrant information

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Ramyar Qaderzade
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-22, 1403/07/01

Expected recruitment end date
2024-10-22, 1403/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation of antimicrobial effect of green tea and chlorhexidine mouthwashes on the frequency of Streptococcus mutans strains in children with removable orthodontic appliances: a randomized clinical trial study

Public title
Effect of green tea and chlorhexidine mouthwash in children with removable orthodontic appliances
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Ensuring the cooperation of participants At least one month has passed since using the removable orthodontic appliance Optimal oral hygiene of the participants Healthy gum and oral environment of participating children Not having systemic disease and cleft palate Not having a report of oral and dental chronic infections in the last year Not reporting any allergy to mouthwash Not having any disability that interferes with the patient's health control
Exclusion criteria:
Participants treated with steroidal and nonsteroidal anti-inflammatory drugs during the past three months Children treated with antiseptic, antibiotic, probiotic or prebiotic drugs during the last three months Non-cooperative participants with less than 8 hours of appliance use per day Rampant caries Use of mouthwash and fluoride therapy during the last month History of radiotherapy
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
4
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants are divided into three groups A, B and C: two groups with clinical intervention(recipient of treatment) and one group as control(recipient of distilled water). Due to the small sample size in this study, the random block method will be used instead of the simple random method to allocate the number of participants to each group. In this method, at first, all possible states will be extracted from blocks of three, and then a number will be assigned to each block. At the end, blocks will be selected using random numbers. This block method helps to have an equal number of participants in each group.
Blinding (investigator's opinion)
Triple blinded
Blinding description
To assign random numbers and perform blinding of patients and researchers, a senior student (who is not involved in the study) is designated as the operator. The operator is responsible for pouring the mouthwash into the bottle and assigning the type of mouthwash to each random number. All mouthwashes for blinding are delivered to the patients in the identical, dark, opaque and unlabeled medicine storage bottles with a volume of 100 ml. Bottles are given to the patient in a parcel, so the contents of the bottles cannot be distinguished by the observer. Only the patient's unique number is written on the mouthwash bottle and the collected saliva sample, and the way the patients are allocated will be kept confidential by the operator until the end of the study. The patient, the researcher, and the statistical analyst are blinded to the contents of the bottles. At the end of the study and performing the statistical comparison between the groups, the operator provides the information related to each of the three studied groups to the statistical analyst so that the final results can be reviewed and compiled.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kordestan University of Medical Sciences
Street address
Pasdaran Street
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6617713446
Approval date
2024-05-19, 1403/02/30
Ethics committee reference number
IR.MUK.REC.1403.031

Health conditions studied

1

Description of health condition studied
Prevalence of Streptococcus mutans bacteria in saliva before and after using mouthwash
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Streptococcus mutans colony count
Timepoint
Before and 15 days after using mouthwash
Method of measurement
Counting bacterial colonies with a colony counter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, the children of the intervention groups are divided into two groups. One group of participants receives 0.2% chlorhexidine mouthwash and another group receives green tea mouthwash. Necessary instructions on how to use mouthwash will be given to the groups receiving the mouthwash. The participants under the intervention use the mouthwash for 15 days and twice a day (at night before bed and in the morning after breakfast) with a volume of 5 ml and for 30 seconds.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Orthodontic Clinic, Faculty of Dentistry, Kurdistan University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

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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
Sanandaj 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
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Sanandaj University of Medical Sciences
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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after unidentified individuals
When the data will become available and for how long
Access starts after publishing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Researchers have access to the data under any circumstances
From where data/document is obtainable
For more information, you can contact the corresponding author via the following email: ramyar.gh01@gmail.com
What processes are involved for a request to access data/document
The applicant has unlimited access to the data after sending the request via email to the corresponding author.
Comments