Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Nov 2026

Comparison of the effect of daily use of mouthwash and toothpaste containing post-biotic on the number of Streptococcus Mutans in the saliva of patients undergoing fixed orthodontic treatment.

Protocol summary

Study aim
Comparison of the effect of daily use of mouthwash and toothpaste containing post-biotic on the number of Streptococcus Mutans in the saliva of patients undergoing fixed orthodontic treatment

Design
Institutional-based, parallel groups, triple-blind, randomized clinical trial. Assignment of patients to study groups will be done using the random block method and using 6 blocks.

Settings and conduct
The research site will be the School of Dentistry of the Ahvaz Jundshapur University of Medical Sciences. Sampling will be performed by the non-probability method. Outcome is measured before the intervention. Participants will be randomly divided into interventions and control groups and after the intervention, the outcome will be measured again. In this study, participants, the person evaluating the results and analyzer of the data will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Good oral hygiene, Good general health, Permanent dentition, DMF (decay, missing, filling)<5 Exclusion criteria: Use of anti-inflammatory drugs or antibiotics in the last month and during orthodontic treatment, Use of products containing Xylitol, Fluoride, Chlorhexidine, and probiotics or post-biotics

Intervention groups
Post-biotic toothpaste group: Participants in this group use toothpaste containing post-biotic twice a day for 4 weeks. Post-biotic mouthwash group: Participants in this group use mouthwash containing post-biotic daily for 4 weeks. Control group: Participants in this group use mouthwash and toothpaste similar to the intervention groups daily for 4 weeks. The only difference between toothpaste and mouthwash used by this group will be the absence of post-biotic.

Main outcome variables
Number of Streptococcus mutans in saliva before intervention, 4 and 8 weeks after intervention

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220504054736N1**
Registration date: **2022-11-30, 1401/09/09**
Registration timing: **prospective**

Last update: **2022-11-30, 1401/09/09**
Update count: **0**

Registration date
2022-11-30, 1401/09/09

Registrant information
Name
Minoo sadat Alavi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 61 3311 2785
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-12-22, 1401/10/01
Expected recruitment end date
2023-04-21, 1402/02/01
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of daily use of mouthwash and toothpaste containing post-biotic on the number of Streptococcus Mutans in the saliva of patients undergoing fixed orthodontic treatment.

Public title
Effect of post-biotic on the number of Streptococcus Mutans in patients undergoing fixed orthodontic treatment.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Good oral hygiene Good general health Permanent dentition DMF (decay, missing, filling)<5 12 years and older
Exclusion criteria:
Use of anti-inflammatory drugs or antibiotics in the last month and during orthodontic treatment Use of products containing Xylitol, Fluoride, Chlorhexidine and probiotics or post-biotics
Age
From **12 years** old
Gender
Both

Phase
3
Groups that have been masked

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

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization: For this purpose, after creating a computer-generated random sequence using Winpepi software, equal blocks of 6 will be used. unit of randomization is individual and randomization tool is sealed envelopes. These steps are performed by an independent statistician who is also responsible for transferring the envelopes containing the treatment code to the pharmacist in charge of the making of the treatment and placebo products.
Blinding (investigator's opinion)
Triple blinded
Blinding description
When entering the study, each of the participants will be given a number, which is transferred to the pharmacist in charge of the making of the treatment and placebo products. The participants, the person evaluating the results of the intervention and the data analyst will not know the type of treatment of the people. Therapeutic products and placebo are packed in exactly the same opaque sealed bags, there is no difference in terms of color, smell and taste, and the label does not specify the nature of the treatment or placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences
Street address
Deputy of research and technology, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2022-11-11, 1401/08/20
Ethics committee reference number
IR.AJUMS.REC.1401.353

Health conditions studied

1

Description of health condition studied
Dental caries
ICD-10 code
K02
ICD-10 code description
Dental caries

Primary outcomes

1

Description
Number of Streptococcus mutans in saliva
Timepoint
before intervention, 4 and 8 weeks after intervention
Method of measurement
Saliva collection and Streptococcus mutans count

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: participants in this group brush their teeth twice a day for 4 weeks, using toothpaste containing post-biotic Bifidobacterium animalis subsp. animalis with a concentration of 2*10^ 9.
Category
Prevention

2

Description
Intervention group: participants in this group wash their mouths daily for 4 weeks, using a mouthwash containing post-biotic Bifidobacterium animalis subsp. animalis with a concentration of 2*10^ 9.
Category
Prevention

3

Description
Control group: Participants in this group use mouthwash and toothpaste similar to the intervention groups daily for 4 weeks. The only difference between toothpaste and mouthwash used by this group will be the absence of post-biotic.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Orthodontics, School of Dentistry
Full name of responsible person
Mashalaah Khanehmasjedi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehrnoush Zaker-Kish
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Deputy of research and technology, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd
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itc@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Minoo sadat Alavi
Position
Resident
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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