

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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)

Phone

+98 61 3311 2785

Email address

minooalavi116@gmail.com

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

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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

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

Medical doctor

Other areas of specialty/work

Dentistry

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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