Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the efficacy of probiotic lozenges containing Streptococcus salivarius on oral malodor and quality of life of patients with halitosis

Protocol summary

Study aim

determine the efficacy of a sublingual probiotic tablet containing Streptococcus salivarius on halitosis and quality of life in patients with halitosis.

Design

This clinical trial includes an intervention group and a control group. The participants will be randomly assigned to the two treatment groups using block randomization performed with dedicated software. The study is triple-blind and will be conducted on 60 patients. For the randomization process, the RAN function in Microsoft Excel was used.

Settings and conduct

School of Dentistry, Alborz University.In the intervention group, participants will receive health education for 5-10 minutes and instructions on how to properly use the probiotic lozenge according to the guidelines.The second group (control) will receive the same 5–10 minute education but will use a placebo lozenge instead of the probiotic. The placebo has the same appearance, taste, and texture but does not contain Streptococcus salivarius bacteria. Both the intervention and control groups will be followed up again at 4 and 8 weeks.This is a triple-blind study:the participant, the evaluator,the healthcare providerand the safety committee.

Participants/Inclusion and exclusion criteria

The inclusion criteria are:.Halitosis confirmed by the assessor using an organoleptic test.Absence of systemic diseases affecting breath odor (e.g., diabetes, liverfailure, gastrointestinal issues).No use of antibiotics or antibacterial mouthwashes in the preceding two weeks.No smoking or alcohol consumption.Not pregnant or breastfeeding.Ability to adhere to the study protocol (e.g., taking the probiotic tablet).

Intervention groups

The intervention consists of administering a probiotic tablet containing Streptococcus salivarius.The control group will receive a placebo tablet

Main outcome variables

Halitosis Severity؛Organoleptic Test؛Tongue Coating Index؛Bad Breath Improvement Test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260413069067N1**
Registration date: **2026-04-16, 1405/01/27**
Registration timing: **prospective**

Last update: **2026-04-16, 1405/01/27**
Update count: **0**

Registration date

2026-04-16, 1405/01/27

Registrant information

Name

Nastaran Najd

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3464 3705

Email address

nastarannajd1993@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-04-21, 1405/02/01

Expected recruitment end date

2026-05-21, 1405/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy of probiotic lozenges containing Streptococcus salivarius on oral malodor and quality of life of patients with halitosis

Public title
Evaluation of the efficacy of probiotic on oral malodor

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
individuals with halitosis confirmed by an examiner using organoleptic testing absence of systemic diseases affecting breath odor (diabetes, liver failure, gastrointestinal issues, etc. no use of antibiotics or antibacterial mouthwashes in the last two weeks no consumption of cigarettes or alcohol, not being pregnant or breastfeeding, and the ability to adhere to the study protocol (consuming probiotic pills)

Exclusion criteria:
Individuals who have halitophobia and halitosis of non-oral origin. Individuals who are taking antibiotics due to other infectious diseases. Individuals due to consumption of cigarettes and other tobacco products, and alcohol.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method will be block randomization, assigning participants to two treatment groups (control and intervention), which will be performed using software.Participants will be randomly assigned to either the intervention or control group using a block randomization method to ensure balanced allocation throughout the study. A computer-generated randomization sequence will be produced using Microsoft Excel’s RANDBETWEEN function (or equivalent random number generator). Fixed block sizes of 4 and 6 will be used in a random order to prevent prediction of group assignments and to ensure equal distribution within each block. The randomization list will be generated by an independent researcher who is not involved in participant recruitment, clinical examination, or outcome assessment. Each allocation code will be placed in opaque, sequentially numbered, sealed envelopes to maintain allocation concealment. During participant enrollment, the next envelope in sequence will be opened by a study coordinator who is blinded to the study hypotheses. The participant will then be assigned to the intervention (probiotic) or control (placebo) group according to the concealed sequence

Blinding (investigator's opinion)
Triple blinded

Blinding description
Participants are invited to join, provide informed consent, and are then randomized into intervention and control groups. They are not informed whether they are receiving the Lactobacillus salivarius probiotic or a placebo, nor are they told which group they are assigned to. The assessor, who confirms the patient's halitosis, is unaware of which patient receives which medication, as they will re-evaluate patients after treatment. The clinical monitor distributes the medications using a randomized list of patient names. This monitor has no knowledge of which patient received which drug and has no contact with the assessor. The data analyst is also not informed about which patient receives which medication, assuming all participants received the intervention, even though some may have received a placebo. The Data Safety Monitoring Board ensures that study participants and all personnel interacting with them remain unaware of the study group assignments

Placebo
Used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Alborz University of Medical Sciences

Street address
Karaj – 45-Meter Golshahr – Safarian Alley – Deputy of Research and Technology

City
Alborz(Karaj)

Province
Alborz

Postal code
3149779453

Approval date
2026-02-25, 1404/12/06

Ethics committee reference number
IR.ABZUMS.REC.1405.009

Health conditions studied

1

Description of health condition studied
oral malodor (Halitosis)
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Halitosis severity (oral malodor)
Timepoint
At baseline, and at weeks 4 and 8
Method of measurement
Assessed through the Halitosis Consultation Hour self-report questionnaire and based on the organoleptic test (evaluation of oral malodor intensity by the examiner's sense of smell, using the nose without any instrument).Scores are interpreted as follows:• 0–1: Normal, no halitosis• >2: Indicates genuine halitosis• >3: Moderate to severe halitosis

2

Description
Halitosis Associated Life-Quality Test
Timepoint
At baseline, and at weeks 4 and 8
Method of measurement
It is a standardized and specialized questionnaire designed to assess the impact of halitosis (oral malodor) on individuals' quality of life.A total score of:• Less than 30: Very little or no impact• 30–45: Mild to moderate impact• 46–60: Moderate to severe impact

3

Description
Self-assessment test for improvement of oral malodor
Timepoint
At baseline, and at weeks 4 and 8
Method of measurement
Assessment of the individual's perception of changes in the severity of oral malodor, based on self-report.Scores are interpreted as follows:• 1: Significantly improved• 2: Improved• 3: No change• 4: Worsened• 5: Significantly worsened

4

Description
Tongue Coating Index
Timepoint
At baseline, and at weeks 4 and 8
Method of measurement
title: Tongue Coating Index for Assessing Dorsal Tongue Plaque CoverageDefinition and scoring:Area assessed: Dorsal surface of the tongueZonal mapping: The tongue dorsum is divided into 6 regionsScoring per region: Each region is scored based on plaque coverageTotal score: Sum of the 6 regional scoresInterpretation of total score:0–4: Oral halitosis unlikely5–9: Commonly observed in oral halitosis10–14: Strong association with oral halitosis15–18: Almost invariably present with oral halitosis

5

Description
Organoleptic Test
Timepoint
At baseline, and at weeks 4 and 8
Method of measurement
Organoleptic Assessment of Oral Malodor IntensityThe intensity of oral malodor is evaluated by the examiner's sense of smell, using the nose directly without any instrumental aid.Scoring criteria:Score 0–1: Normal, no halitosisScore ≥2: Indicates genuine halitosisScore ≥3: Represents moderate to severe halitosis

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention ProcedureIn the intervention group, participants receive a 5–10 minute, face-to-face oral hygiene instruction session delivered by a senior (final-year) dental student who is not involved in the organoleptic assessment process. The educational session covers essential principles of oral hygiene, including the correct tooth-brushing technique, proper use of dental floss, and tongue cleaning using a tongue scraper. The tongue scraper provided is a U-shaped plastic device.Following oral hygiene instruction, patients are educated on the proper use of the probiotic lozenge according to the manufacturer's guidelines. They are instructed to chew one probiotic lozenge completely every night before bedtime, after brushing their teeth, and to avoid eating or drinking anything until the next morning.The probiotic lozenge (Lactogum), manufactured by Zist-Takhmir Company, contains more than 10910 9 CFU of Streptococcus salivarius strains, including 150 mg of strain K12 and 150 mg of strain M18.Participants in the intervention group are re-evaluated at weeks 4 and 8. Each follow-up visit includes: assessment of any potential adverse effects, verification of the consumption of prohibited medications, and monitoring of oral malodor using standardized oral-hygiene–related indices. These assessments consist of the Tongue Coating Index, the organoleptic test, the HALT quality-of-life questionnaire, and the Bad Breath Improvement self-assessment test (BBI) following the intervention.Additionally, participants receive a follow-up chart (Appendix 3) to record their daily oral hygiene practices, including the number of tooth-brushing episodes, flossing frequency, and lozenge

consumption. This chart is collected at the 4-week and 8-week follow-up visits for data recording.

Category

Treatment - Drugs

2

Description

Control group: Control Group ProcedureParticipants in the control group receive a 5–10 minute oral hygiene instruction session covering the essential principles of oral hygiene, including proper tooth-brushing technique, correct use of dental floss, and tongue cleaning with a tongue scraper (a U-shaped plastic device).In this group, instead of the probiotic lozenge, participants are given a placebo lozenge that is identical in appearance, taste, and texture but contains no Streptococcus salivarius strains.Participants in the control group are re-evaluated at weeks 4 and 8. Each follow-up visit includes: assessment of any potential adverse effects, verification of the consumption of prohibited medications, and monitoring of oral malodor using standardized oral-hygiene–related indices. These assessments consist of the Tongue Coating Index, the organoleptic test, the HALT quality-of-life questionnaire, and the Bad Breath Improvement self-assessment test (BBI) following the intervention.Additionally, participants receive a follow-up chart (Appendix 3) to record their daily oral hygiene practices, including the number of tooth-brushing episodes, flossing frequency, and lozenge consumption. This chart is collected at the 4-week and 8-week follow-up visits for data recording.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alborz School of Dentistry

Full name of responsible person

Nastaran Najd

Street address

Karaj – 45-Meter Golshahr Avenue – Ketouyi-zadeh Square – School of Dentistry

City

Karaj

Province

Alborz

Postal code

3198684868

Phone

+98 26 3350 0080

Email

Nastarannajd1993@gmail.com

Web page address

https://dentistry.abzums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zist-Takhmir Pharmaceutical Company

Full name of responsible person

Sahar Bahmani

Street address

No. 56, Hayamanesh St., Dabestan St., Seyed Khandan Bridge, Tehran, Iran**

City

Tehran

Province

Tehran

Postal code

1683848411

Phone

+98 21 8846 2023

Email

zisttakhmir@gmail.com

Web page address

https://zisttakhmir.com/contact

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zist-Takhmir Pharmaceutical Company

Proportion provided by this source

20

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Nastaran Najd

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Dentistry

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Karaj – 45-Meter Golshahr Avenue – Ketouyi-zadeh Square – School of Dentistry

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Nastaran Najd
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Dentistry
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Person responsible for updating data

Contact
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
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Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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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
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 datasets will be eligible for sharing once all personally identifiable information has been fully removed.
When the data will become available and for how long
Data access will be initiated six months after the results have been published.
To whom data/document is available
The data will be available to researchers affiliated with academic and scientific institutions, and individuals working in industry may also apply to access them.
Under which criteria data/document could be used
The dissemination of documents requires proper citation of the source and an honest, unbiased reporting of the results.
From where data/document is obtainable
Principal Investigator: Nastaran Najad Phone: +98-912-724-6319 Address: Alborz School of Dentistry, Katoui-zadeh Square, Karaj, Iran Postal Code: 3198684868
What processes are involved for a request to access data/document
Direct contact by phone or SMS is required, accompanied by a clear and transparent explanation of the nature of the request, the requesting organization and individual, and the intended use of the data. Upon approval, the requested information will be provided within 24 hours.
Comments