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The potential effects of probiotic mouth rinse on halitosis in a sample of dental students

Submission date
09/06/2025

Recruitment status
No longer recruiting

Registration date
22/06/2025

Overall study status
Completed

Last Edited
19/06/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Halitosis (bad breath) is associated with considerable social embarrassment, especially in younger individuals. This study aims to find out whether probiotics can reduce halitosis and achieve a reduction in certain bacteria.

Who can participate?
Dental students from the College of Dentistry/University of Sulaimani with halitosis

What does the study involve?
The participants will be instructed to use the probiotic mouth rinse for 2 weeks and three samples of saliva will be obtained to assess the effect of the product on certain bacteria. After that, the participants will be divided into two groups based on the severity of their tongue coating. The possible effect of probiotic mouth rinse on halitosis and certain bacteria will be evaluated.

What are the possible benefits and risks of participating?
The probiotic mouth rinse may be beneficial for halitosis with no known risks to health.

Where is the study run from?
University of Sulaimani (Iraq)

When is the study starting and how long is it expected to run for?
December 2024 to December 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Khadija M Ahmed, khadija.ahmad@univsul.edu.iq

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The effectiveness of probiotic mouth rinse in alleviating halitosis clinically and its impact on three strains of bacteria in a sample of dental students

Study objectives
Probiotic mouth rinse could have effects on halitosis clinically and microbiologically. The null hypothesis is that probiotic mouth rinse has no effect in treating halitosis.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/11/2023, The Ethics Committee of the College of Dentistry (University of Sulaimani, Madam Mitterrand Street, Sulaymaniyah, 46001, Iraq; +964 (0)7704522890; dentistry.ethics@univsul.edu.iq), ref: 204/23

Study design
Single-center observational cross-sectional study

Primary study design
Observational

Study type(s)

Efficacy

Health condition(s) or problem(s) studied
Halitosis

Interventions
Participants will be selected from dental students of the college of dentistry with genuine halitosis and coated tongue.
Patients will be instructed to use probiotic mouth rinse two times per day and will be instructed not to eat or drink anything and not conduct any oral hygiene activities for at least 1 h.

Neither professional prophylaxis nor toothbrushing instructions will be performed during or before the experimental period. Maintenance of this regime will be confirmed at days 1, 7 and 15 of the study .

Malodor will be assessed, clinical parameters will be recorded, and the whole stimulated saliva samples will be obtained from all participants at baseline and days 1, 7 and 15 of the study.

Organoleptic (OLT) score, area of tongue coating (Ta), thickness of tongue coating (Tt), and malodor assessment will be conducted by a single dentist. The OLT score and tongue coating will be evaluated as the major outcomes. Assessments will be conducted in the morning between 8:00 and 10:00 am. In the 24 h before odour testing, the patients will not be allowed to eat onions, garlic, leeks, and other odorous foods, or to drink alcohol. In the 2 h before testing, the patients also will not be allowed to eat, to drink beverages, to chew gum, or to brush their teeth.

The OLT score includes a scale of 0 to 5. The patients closed their mouths for 1 min and then exhaled slowly from their mouths into the clinician’s face from a 10-cm distance. The score will be evaluated as follows: 0 = none, 1 = barely noticeable, 2 = slight but clearly noticeable, 3 = moderate, 4 = strong offensive, and 5 = extremely foul. The reduction of the OLT score will be considered to be effective.

The area and thickness of tongue coating will be determined by inspection. Ta will be determined on a scale of 0–3 (0, none visible; 1, less than one-third of tongue dorsum surface covered; 2, less than two-thirds; and 3, more than two-thirds). Tt will be recorded as a score of 0–2 (0, no tongue coating; 1, thin tongue coating: tongue papillae visible; and 2, thick tongue coating: tongue papillae invisible). Then, the tongue coating score (TCS) will be obtained by multiplying Ta by Tt.

For the microbiological examination, the prevalence of L. salivarius, periodontopathic bacteria producing volatile sulphur compounds (VSCs), including P. gingivalis, and cariogenic bacteria, including Streptococcus mutans, will be determined by polymerase chain reaction (PCR) and the amount of L. salivarius in the saliva will be determined by real-time PCR.

Intervention Type
Mixed

Primary outcome(s)
Halitosis determined clinically using organoleptic (OLT) score and tongue coating score [area of tongue coating (Ta), thickness of tongue coating (Tt)] at baseline day 1, 1 and 2 weeks (day 7 and 15) after administration of the mouth rinse

Key secondary outcome(s))
Strains of bacteria evaluated by examining the whole stimulated saliva using real-time PCR at days 1, 7 and 15

Completion date
21/12/2025

Eligibility

Key inclusion criteria
1. Willing to be included in the study
2. Halitosis proven by OLT measure with tongue coating

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
19 years

Upper age limit
25 years

Sex
All

Total final enrolment
35

Key exclusion criteria
1. Those who dislike being part of the study
2. Use of antibiotics in the previous 3 months
3. Systemic illnesses

Date of first enrolment
22/12/2024

Date of final enrolment
20/12/2025

Locations

Countries of recruitment
Iraq

Study participating centre
University of Sulaimani
College of Dentistry
Baxtiary
Iraq
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Sponsor information

Organisation
University of Sulaimani

ROR
https://ror.org/00saanr69

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data analyzed during the study period will be available upon request from Dr Khadija M Ahmed (khadija.ahmad@univsul.edu.iq).
Dates of availability: after completing the analysis.
Consent was obtained from the participant before starting the study.
The data collection is confidential, and for transparency and upon reasonable request the analysed data would be available publicly.

IPD sharing plan summary
Available on request