Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of probiotic tablets and probiotic enriched yogurt on halitosis :a crossover clinical trial

Protocol summary

Study aim
Comparison of the effect of probiotic tablets and probiotic enriched yogurt on halitosis

Design
This is a randomized clinical trial, phase 2-3 is in the form of a crossover. This single-blinded study will be conducted on 42 patients diagnosed with halitosis eligible to participate in the study. A randomized Simple randomization method is used for randomization and participants are assigned to two intervention groups.

Settings and conduct
This study, which will be conducted in the dental clinic of Kermanshah city, is single-blinded, and the outcome evaluators are kept blind to the allocation of the study groups. Before the intervention, the halitosis is measured by a Halimeter. After the 14-day period, the halitosis is recorded by the Halimeter, and after a 14-day rest period, the groups are switched and this time the first group consumes the probiotic yogurt and vice versa.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Acknowledgment of halitosis that has been confirmed by the examiner or the person's relatives; Informed consent; At least 15 years old; Maintaining oral hygiene in the form of brushing at least once a day Exclusion criteria: Cigarette and tobacco smoking; Suffering from systemic and digestive diseases; Pregnancy and breastfeeding; Sinusitis and respiratory diseases; Allergy to dairy products; Complete toothlessness

Intervention groups
The first intervention group dissolves a probiotic pill in the mouth at night after brushing and then eats it for 14 days. The second intervention group consumes 100 ml of probiotic yogurt once a day after a meal for 14 days.

Main outcome variables
Halitosis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N193**
Registration date: **2023-01-27, 1401/11/07**
Registration timing: **prospective**

Last update: **2023-01-27, 1401/11/07**
Update count: **0**

Registration date
2023-01-27, 1401/11/07

Registrant information

Name
Feizollah Foroughi

Name of organization / entity
kermanshah University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 83 1821 4653

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fforoughi@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-11, 1401/11/22

Expected recruitment end date
2023-05-12, 1402/02/22

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of probiotic tablets and probiotic enriched yogurt on halitosis :a crossover clinical trial

Public title
Comparison of the effect of probiotic tablets and probiotic enriched yogurt on halitosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Acknowledgment of real bad breath that has been confirmed by the examiner or the person's relatives Informed consent At least 15 years old Maintaining oral hygiene in the form of brushing at least once a day

Exclusion criteria:
Cigarette and tobacco smoking Suffering from systemic and digestive diseases Pregnancy and breastfeeding Sinusitis and respiratory diseases Allergy to dairy products Complete toothlessness

Age
From **15 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the simple random method. The names of the participants are written on the card. The cards are put into a box that cannot be seen from outside. One of the colleagues of the plan is asked to remove one card from the container at a time. The names of the 21 cards that are selected first are placed in the first intervention group, the second 21 selected cards are placed in the second intervention group.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the outcome assessors are blinded to the study group allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences

Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2023-01-03, 1401/10/13

Ethics committee reference number
IR.KUMS.REC.1401.412

Health conditions studied

1

Description of health condition studied
Halitosis

ICD-10 code
R19.6

ICD-10 code description
Halitosis

Primary outcomes

1

Description
Halitosis

Timepoint
The beginning of the study, 14 days after the start of the intervention, the end of the study (28 days after the intervention)

Method of measurement
Using a Holimeter

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group dissolves a probiotic pill in the mouth at night after brushing and then eats it for 14 days.

Category
Treatment - Other

2

Description
The second intervention group consumes 100 ml of probiotic yogurt once a day after a meal for 14 days
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry
Full name of responsible person
Negar Eyvazi
Street address
Faculty of Dentistry, Shariati Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Cyrus Jalili
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard
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cjalili@kums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Negar Eyvazi
Position
Dental student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
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Person responsible for scientific inquiries

Contact
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Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Narges Ziaei
Position
Member of the faculty of Kermanshah University of Medical Sciences
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Negar Eyvazi

Position
Dental student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available