Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Production and investigation of antibacterial effects of chewing gum containing postbiotic yeast Saccharomyces boulardi and its chewing effect on Streptococcus mutans levels in human saliva: a randomized controlled trial

Protocol summary

Study aim
The purpose of this study is to investigate the effect of postbiotic consumption of Saccharomyces boulardi on the number of Streptococcus mutans bacteria in the mouth.

Design
Clinical trial including three groups of participants with a parallel design, three blind strains, randomized, phase three on 90 people. Sealed envelope lottery will be used for randomization.

Settings and conduct
The participants will be selected from among the staff of resaerch deputy of Alborz University of Medical Sciences and their families. The saliva sample of the eligible people is collected and then according to the person's lottery, they are placed in one of the test groups, and the chewing gum with the selected code will be provided to the person in the amount necessary for consumption for ten days. Then the person will use this gum twice a day for ten days. The gums of the three groups have the same appearance and none of the participants, researchers and the person who performs the statistical analysis work will know the assignment of people to the groups. After ten days, saliva samples will be collected and the number of Streptococcus mutans bacteria in the saliva samples will be counted and compared in three groups.

Participants/Inclusion and exclusion criteria
All people aged 15 to 40 who do not have active oral disease and are not allergic to gum compounds and have not used food products containing probiotics during the two weeks prior to the study can enter the study.

Intervention groups
This study will have three groups of participants. A group of regular chewing gum, a group of chewing gum containing postbiotics, and a group of chewing gum containing xylitol who will consume it twice a day for 20 to 30 minutes for ten days.

Main outcome variables
Streptococcus mutans bacteria count in saliva

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160117026069N10**
Registration date: **2024-01-27, 1402/11/07**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-27, 1402/11/07**
Update count: **0**

Registration date
2024-01-27, 1402/11/07

Registrant information

Name
Fereshteh Ansari

Name of organization / entity
Razi Vaccine and Serum Research Institute

Country
Iran (Islamic Republic of)

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+98 26 3405 0400

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-27, 1402/11/07

Expected recruitment end date
2024-02-26, 1402/12/07
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Production and investigation of antibacterial effects of chewing gum containing postbiotic yeast Saccharomyces boulardi and its chewing effect on Streptococcus mutans levels in human saliva: a randomized controlled trial

Public title
Investigating the effect of chewing gum containing postbiotic on the number of Streptococcus mutans bacteria in saliva
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
All adults between 15 and 40 years old
Exclusion criteria:
People who have been treated with antibiotics within two weeks before the start of the study Individuals with any active dental or gum disease within two weeks prior to the start of the study People who are allergic to any of the gum compounds
Age
From **15 years** old to **40 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: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Sealed envelopes are considered as the number of patients, whose content determines which group each person belongs to. One of these envelopes is selected for each patient by lottery, and then this envelope is opened and the allocation of the patient will be determined after opening the envelopes.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, the gums of all three groups are similar to each other and only the code assigned to them is different. Participants, clinical examiners, researchers, and laboratory personnel who have access to the collected samples and data, as well as the person performing the statistical analysis will be blinded to the coding of the groups until the disclosure of the codes after statistical analysis.
Placebo
Not used
Assignment
Parallel
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
Saffarian Alley, Golshahr Blvd, Karaj
City
Karaj
Province
Alborz
Postal code
3198764653
Approval date
2023-12-02, 1402/09/11
Ethics committee reference number
IR.ABZUMS.REC.1402.281

Health conditions studied

1

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

Primary outcomes

1

Description
Streptococcus mutans bacteria count in saliva
Timepoint
Before the study, ten days after the study
Method of measurement
Culture and bacterial count

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Normal gum, twice a day for ten days
Category
Prevention

2

Description
Intervention group: Gums containing postbiotic, twice a day for ten days
Category
Prevention

3

Description
Control group: Gums containing xylitol, twice a day for ten days
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Research deputy of Alborz university of medical science
Full name of responsible person
Hadi Pourjafar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Razieh Lotfi
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Vice-Chancellor for Research and Technology, Golshahr, Safarian Alley
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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
Karaj 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
Karaj University of Medical Sciences
Full name of responsible person
Hadi Pourjafar
Position
Associate Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Assistant professor
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Epidemiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
After submitting the request to the project manager, this request will be reviewed by a committee with the presence of all the people involved in the project, and then if the committee gives a positive answer, the data will be provided to the applicant.
When the data will become available and for how long
Access starts 6 months after results are published
To whom data/document is available
All researchers working in academic and scientific institutions and people working in the industry
Under which criteria data/document could be used
If a request with this theme is received, a decision will be made with the opinion of the research team.
From where data/document is obtainable
From the project manager, Dr. Hadi Pourjafar
What processes are involved for a request to access data/document
After submitting the request to the project manager, this request will be reviewed by a committee with the presence of all the people involved in the project, and then if the committee gives a positive answer, the data will be provided to the applicant.
Comments