

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 research 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)

Phone

+98 26 3405 0400

Email address

ansarif@ut.ac.ir

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 boulardii* 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

AgeFrom **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 sizeTarget 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

Street address

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

Ph.D.

Other areas of specialty/work

Food safety and Health

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Nadia Sadeghi

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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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**Person responsible for updating data****Contact****Name of organization / entity**

Razi Vaccine and Serum Research Institute

Full name of responsible person

Fereshteh Ansari

Position

Assistant professor

Latest degree

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Other areas of specialty/work

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