Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

: The effect of probiotics on salivary pH and flow rate in healthy subjects, A double blinded, randomized, controlled trial

Protocol summary

Study aim
Determining the effect of probiotics on salivary pH and flow rate in healthy subjects

Design
The clinical trial has a control group, with parallel groups, double-blinded, randomized, phase 4 on 60 individuals. Random number table was used for randomization

Settings and conduct
Saliva samples are taken from the participants and their pH and weight are measured immediately after collection. Then group 1people are given 30 probiotic pills for one month. In group two, we use 30 placebo pills. At the end of one month, individuals in both groups are recalled and pH and saliva volume are measured. At the end of the intervention, a one-month follow-up is considered. For the principal investigator, participants, and analyst, the content of the tablets is blinded by randomly assigning codes one and two to the intervention and comparison groups in a separate center.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Healthy people aged 20 to 40 who fill out an informed consent form؛ Exclusion criteria: Presence of a marked systemic disease؛ History of smoking and alcohol consumption؛ Pregnancy and lactation status؛ Patients with complete edentulousness؛ There are specific symptoms of dry mouth, including fissure lip and palate, rampant caries, fungal infections, adhesions of the tongue and mucous membranes to the teeth, etc؛ History of consumption of other products containing probiotic in the past month؛ History of taking any medication, including antibiotics, antiseptics, Saliva reducing or increasing drugs in the past month

Intervention groups
In the intervention group, probiotic lozenges were used as a medicine. People take one of these pills a day for 30 days. In the comparison group, we use 30 placebo pills that have the same shape, color and composition as the previous pills but without probiotic content.

Main outcome variables
Number of digital scales؛ number of digital pH meter

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210112050013N1**
Registration date: **2021-03-02, 1399/12/12**
Registration timing: **prospective**

Last update: **2021-03-02, 1399/12/12**
Update count: **0**

Registration date
2021-03-02, 1399/12/12

Registrant information

Name
Javid Rasekhi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-16, 1399/12/26

Expected recruitment end date
2021-05-16, 1400/02/26

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title

: The effect of probiotics on salivary pH and flow rate in healthy subjects, A double blinded, randomized, controlled trial

Public title

The effect of probiotics on salivary pH and flow rate

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy people aged 20 to 40 who fill out an informed consent form

Exclusion criteria:

Presence of a marked systemic disease History of smoking and alcohol consumption Pregnancy and lactation status Patients with complete edentulousness There are specific symptoms of dry mouth, including fissure lip and palate, rampant caries, fungal infections, adhesions of the tongue and mucous membranes to the teeth, etc History of consumption of other products containing probiotics in the past month History of taking any medication, including antibiotics, antiseptics, Saliva reducing or increasing drugs in the past month

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize, the layering method will be used, in which people are first, divided into four layers based on age and gender, and randomization will be done in each layer. Also, to create a balance in the samples allocated in each of the layers, the block randomization method will be used (The blocks will be formed using a table of random numbers and assigning code 1 to even numbers and code 2 to odd numbers and moving left to right in each layer).In this way, the extracted codes will be placed in sealed envelopes and when each participant enters the study, according to the mentioned layer, the envelopes of that layer will be randomly assigned to him. And according to the assigned codes in an independent center, the decision to allocate the main drug and placebo will be made (intervention and control).At all stages of the study, neither the participants nor the outcome assessment officials are aware of the groups and only follow the study based on the assigned codes and record the consequences.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drugs and placebo in a separate center are marked with codes one and two assigned to the accident without informing the research team (participants, principal investigator and analyst).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of North Khorasan University of Medical Sciences

Street address

Al-Zahra Student Dormitory، Block 1، Alley 6، Shahriyar St.، Al-Ghadir Complex

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bojnurd

Province

North Khorasan

Postal code

9415837413

Approval date

2021-01-11, 1399/10/22

Ethics committee reference number

1399.100.IR.NKUMS.REC

Health conditions studied

1

Description of health condition studied

Saliva flow rate

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Saliva pH

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Number of digital scales

Timepoint

Measurement of salivary flow rate at the beginning of the

study (before the intervention), one and two months after the start of probiotic use

Method of measurement

Digital scale device

2

Description

Number digital pH meter

Timepoint

Measurement of saliva pH at the beginning of the study (before the intervention), one and two months after the start of probiotic use

Method of measurement

Digital pH meter

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, lactogam probiotic lozenges containing Streptococcus salivarius K12 and Streptococcus salivarius M18, (CFU <109) with natural mint flavor and without sugar, produced by Zist Takhmir Company, were used as a medicin. People take one of these pills a day for 30 days. In this way, the person puts the pill in his mouth and allows the pill to dissolve completely in his mouth and then does not want to eat or drink for at least an hour.

Category

Treatment - Drugs

2

Description

In the comparison group, we use 30 placebo pills that have the same shape, color and composition as the previous pills but without probiotic content (placebo lozenges containing starch with natural mint flavor and no sugar).These pills are taken in the same way as the previous group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of the School of Dentistry, North Khorasan University of Medical Sciences

Full name of responsible person

Javid Rasekhi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Amir Amani

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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

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Javid Rasekhi

Position

Assistant Professor

Latest degree
Specialist
Other areas of specialty/work
Dentistry
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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available