

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of the effects of Streptococcus salivarius M18 and K12 probiotic bacteria on the amount of Streptococcus mutans in saliva: a randomized clinical trial

Protocol summary

Study aim

The aim of this study was to evaluate the effect of short-term use of probiotics containing Streptococcus salivarius K12 and M18 bacteria on salivary Streptococcus mutans in order to evaluate their effectiveness in reducing tooth decay.

Design

A randomized controlled clinical trial with a parallel group design of 40 patients. Block method and random allocation software were used for randomization.

Settings and conduct

The place of sampling and examination of people is in the School of Dentistry of Isfahan University of Medical Sciences. Saliva samples are taken from individuals before and after the intervention and cultured, and bacterial colonies are counted.

Participants/Inclusion and exclusion criteria

Entry requirements: people without orthodontic appliances or six months after the end of orthodontic treatment; people who have not taken antibiotics in the past month; people who do not have incomplete dental treatment; people without immune system diseases. No entry conditions: people with orthodontic appliances or people who have had orthodontic treatment for less than six months; people who have taken antibiotics in the past month; people undergoing incomplete dental treatment; people with immune system diseases.

Intervention groups

Probiotic products containing Salivarius M18 and K12 are claimed to be useful in preventing dental caries, however, little research is available to conclusively prove this. This study was designed to evaluate the efficacy of these probiotic substances. The control group in this study also took oral deodorant tablets with the same taste and consistency as the intervention group tablets.

Main outcome variables

The amount of Streptococcus mutans in saliva; the

plaque index of individuals

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210811052147N1**

Registration date: **2021-10-17, 1400/07/25**

Registration timing: **prospective**

Last update: **2021-10-17, 1400/07/25**

Update count: **0**

Registration date

2021-10-17, 1400/07/25

Registrant information

Name

Mohammad reza esrafilii bishe

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3663 1299

Email address

esrafilii77@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-20, 1400/07/28

Expected recruitment end date

2021-11-19, 1400/08/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of Streptococcus salivarius M18 and K12 probiotic bacteria on the amount of Streptococcus mutans in saliva: a randomized clinical trial

Public title

Evaluation of the effects of Streptococcus salivarius M18 and K12 probiotic bacteria on the amount of Streptococcus mutans in saliva: a randomized clinical trial

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

People without orthodontics or people who have had orthodontic treatment for more than six months People who have not taken antibiotics in the past month People who do not have incomplete dental treatment People without immune system diseases

Exclusion criteria:

People with orthodontic appliances or people who have had orthodontic treatment for less than six months People who have taken antibiotics in the past month People undergoing incomplete dental treatment People with immune system diseases

Age

From **19 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are randomly divided into 2 groups of 20 people. In order to maintain the equality of the number of people in both groups, in this study, the limited randomization method of block randomization will be used. Blocking is usually used to balance the number of samples assigned to each of the study groups. This feature helps researchers to equate the number of samples assigned to each of the study groups in cases where intermediate analyzes are required during the sampling process. The size of all the blocks is the same and in this two-group experiment we will have 40 blocks of 20 people including 20 people in the probiotic group and 20 people in the control group (mouth freshener pill). The randomization tool will be the latest version of random allocation software, which in addition to simple randomization will also be able to block randomization. We also use allocation concealment, which is the method used to execute random sequences on study participants so that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed

with random sequence (Sequentially numbered, sealed, opaque envelopes) in which in this method each random sequence is recorded on a card and the cards are inside the envelopes respectively. Are placed. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Boulevard, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-10-12, 1400/07/20

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.297

Health conditions studied**1****Description of health condition studied**

Dental caries

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes

1

Description

The amount of Streptococcus mutans in saliva

Timepoint

Saliva samples are collected at the beginning and end of the intervention.

Method of measurement

Bacteria are measured based on colony count

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: to standardize oral hygiene, both intervention and control groups are given brushing training one week before the intervention. People also use a type of toothpaste for a week before the intervention and at the end of the entire intervention period. Individuals take a tablet containing the probiotic bacteria Streptococcus salivarius M18 and K12 in their mouth every night before going to bed and suck it until it dissolves and consume this substance for 20 days. This tablet is under the brand name of Lactogam and is a product of Zist Takhmir Company and is made in Iran. These tablets contain 150 mg of M18 bacteria and 150 mg of K12 bacteria. Also, more than 10 to the power of 9 colonies of these bacteria are present in each tablet. The taste of this pill is mint.

Category

Prevention

2

Description

Control group: to standardize oral hygiene, both intervention and control groups are given brushing training one week before the intervention. People also use a type of toothpaste for a week before the intervention and at the end of the entire intervention period. Individuals put a mouthwash pill in their mouth at night before going to bed and suck it until it dissolves and consume this substance for 20 days. This pill is under the brand name of Iceberg and made in Iran in Shiva food industry. The sweetener in this pill is xylitol and it is unusable for bacteria in the mouth. Also, the dose of xylitol in each deodorant pill is extremely low and has no therapeutic effect of xylitol. The taste of this pill is mint.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry of University of Medical Sciences of Isfahan

Full name of responsible person

Firoozeh Nilchian

Street address

School of Dentistry , Isfahan University of Medical Sciences , Hezar Jarib Boulevard, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5594

Email

f_nilchian@dnt.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Isfahan University of Medical Sciences , Hezar Jarib Boulevard, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8138

Email

sh_haghjoo@med.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Firoozeh Nilchian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

School of Dentistry , Isfahan University of Medical Sciences , Hezar Jarib Boulevard, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5594

Email

f_nilchian@dnt.mui.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Firoozeh Nilchian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

School of Dentistry , Isfahan University of Medical Sciences , Hezar Jarib Boulevard, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5594

Email

f_nilchian@dnt.mui.ac.ir

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

Esfahan University of Medical Sciences

Full name of responsible person

Firoozeh Nilchian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

School of Dentistry , Isfahan University of Medical Sciences , Hezar Jarib Boulevard, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5594

Email

f_nilchian@dnt.mui.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All our data except people names and phone numbers can be published

When the data will become available and for how long

The data will be available 1 year after the results are published.

To whom data/document is available

The data is accessible to academic researchers and industry researchers. It should be noted that this information will be available only to Iranian universities and companies.

Under which criteria data/document could be used

If the data is not deleted and changed and the purpose of using the data is clear to the early researchers, it is possible to use the data at the discretion of the early researchers. It should be noted that in case of any discrepancy with moral principles or having bad intentions, this information will not be provided to individuals.

From where data/document is obtainable

Dr. Firoozeh Nilchian Address: School of Dentistry, Isfahan University of Medical Sciences Phone: 00983137925594 Email: f_nilchian@dnt.mui.ac.ir Postal Code: 8174673461

What processes are involved for a request to access data/document

The application must be mentioned by phone number or

email. Then, if the initial researchers agree, the necessary information will be provided to the applicants

as soon as possible.
Comments