

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparative evaluation of Probiotic lozenges tablets with Mouthwash containing fluoride and cetyl pyridinium chloride and chewing gum containing Xylitol on oral Streptococcus mutans coloni

Protocol summary

Study aim

Comparative evaluation of Probiotic lozenges tablets with Mouthwash containing fluoride and chewing gum containing Xylitol on oral Streptococcus mutans coloni.

Design

Clinical efficacy with three intervention groups, with parallel groups, randomized, on 72 volunteers, random permutation block method will be used for randomization.

Settings and conduct

The volunteers will be selected from the dental students of Rafsanjan University of Medical Sciences. Sampling will be done by a non-provocation method of volunteers: The first group will be given probiotic lozenges, the second group will be given fluoride and cetylpyridinium chloride mouthwash, and the third group will be given xylitol chewing gum. Sampling of patients will be done before the intervention and also on days 2, 14 and 30 after the intervention and the level of Streptococcus mutans saliva will be measured in each period.

Participants/Inclusion and exclusion criteria

Exclusion criteria: suffering from any kind of systemic disease; using contraceptive pills and being pregnant; using orthodontic appliances and brackets, fixed and removable prostheses; the existence of sensitivity to probiotic products or other elements included in the study; suffering from rapid progressing caries are acute periodontal and gum diseases. Entry criteria: proper oral hygiene; the presence of at least 6 healthy teeth in each jaw.

Intervention groups

group A receives a Lactogam lozenge daily immediately after brushing. group B receives 15 mg of Vivaan alcohol-free general mouthwash (0.05%) twice a day. group C consume Miradent xylitol gum four times a day.

Main outcome variables

The number of Streptococcus mutans colonies

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231127060200N1**

Registration date: **2024-03-04, 1402/12/14**

Registration timing: **prospective**

Last update: **2024-03-04, 1402/12/14**

Update count: **0**

Registration date

2024-03-04, 1402/12/14

Registrant information

Name

Ali Nabavizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 34 3428 4991

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-02, 1403/01/14

Expected recruitment end date

2024-05-03, 1403/02/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of Probiotic lozenges tablets with Mouthwash containing fluoride and cetyl pyridinium chloride and chewing gum containing Xylitol on oral Streptococcus mutans coloni

Public title

evaluation of Probiotic lozenges, fluoride Mouthwash and Xylitol gum on Streptococcus mutans

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Proper oral hygiene (brush at least twice a day) The presence of at least 6 healthy teeth in each jaw without caries or complex restorations and crowns

Exclusion criteria:

Suffering from any systemic disease Use of any type of antibiotic and probiotic products during the last month Fluoride therapy and use of fluoride or antibacterial mouthwash during the last two weeks Using birth control pills and being pregnant Use of orthodontic devices and brackets, fixed and mobile prosthesis Presence of sensitivity to probiotic products or other elements in the study such as fluoride or xylitol Suffering from rapidly progressive caries, acute periodontal and gum diseases. smoking

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

People will be divided into 3 equal groups using random permutation block method. In this study, blocks of 9 will be used in such a way that three cards will be prepared for each group (9 cards in total) and letters A, B and C will be written on the cards, which represent the first, second and third groups. Then, when the first person enters the study, one of the 9 selection cards will be randomly selected and the person will be placed in the same group. When the second person enters, one of the remaining 8 selection cards will be selected and the person will be placed in the specified group. The process will be repeated until all 9 cards are selected (first block) and people 10 to 18 who are the second block will be placed in three groups (three people in each group) like the first block, and this process will be repeated up to 72 people. By using this method, in addition to randomly placing people in groups, the number in the three groups will be exactly equal.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Rafsanjan University of Medical Sciences

Street address

Rafsanjan - Imam Ali Boulevard - Central Organization

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Rafsanjan

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Kerman

Postal code

7717933777

Approval date

2022-12-07, 1401/09/16

Ethics committee reference number

ir.rums.rec.1401.175

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

Dental caries

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The average number of Streptococcus mutans colonies

Timepoint

Sampling of patients will be done before the intervention and also on the 2nd, 14th and 30th days after the intervention.

Method of measurement

Sampling of saliva by non-stimulating method and culture

Secondary outcomes

empty

Intervention groups**1****Description**

The first intervention group: they will receive one lactogam lozenge daily (a product of Lactogam Company (Tehran-Iran)) immediately after brushing their teeth, and they will be asked to continue sucking the lozenge for about half an hour and avoid swallowing it quickly. They are asked not to eat, drink or have a snack for half an hour after taking the pill.

Category

Prevention

2**Description**

The second intervention group: this group is asked to keep 15 mg of mouthwash (Vivaan alcohol-free General mouthwash produced by Rogin Company (Tabriz-Iran)) twice a day (after breakfast and before bed after brushing teeth) for 60 seconds. and avoid eating and drinking for at least half an hour afterwards.

Category

Prevention

3**Description**

The third intervention group: This group is asked to consume Miradent xylitol gum (Hager pharma-Disburg-Germany), consume four pieces of gum daily after breakfast, lunch, snack and dinner and continue chewing it for at least 5 minutes. .

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Faculty of Dentistry, Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Ali Nabavizadeh

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West Shahid Mofateh Blvd., next to Aliebn Abitaleb Hospital

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

رضا وزیری نژاد

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Rafsanjan 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**

Rafsanjan University of Medical Sciences

Full name of responsible person

Ali Nabavizadeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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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