Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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alinabavizadeh@gmail.com

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

City
Rafsanjan

Province
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 Nabavizade

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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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