Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

comparison of the effect of probiotic yogurt and gums containing xylitol on salivary mutans streptococcus reduction

Protocol summary

Summary

Objective of the study: a comparison between the impact of probiotic yoghurt and xylitol-containing chewing gum on the reduction of Streptococcus mutans of saliva.Study design: randomized clinical trial .Population: selected among the resident students in female dormitory of Islamic Azad University of khorasgan.Inclusion criteria: lack of any systemic diseases, having ≥150 forming units of Streptococcus mutans colony in 1 ml of saliva .Exclusion criteria: use of any types of antibiotics and medications containing corticostroide and antibacterial mouthwash and topical Fluoride (except Fluoridated toothpaste) 4 weeks before study starts, regular use of probiotic products and Xylitol-containing gums, smoking and taking contraceptive drugs.Sample size: 50 participants.Interventions: participants are randomly divided to 2 groups; group 1 will have probiotic yoghurt and group 2 will have xylitol gum . Intervention time:3 Weeks.Study implication: reducing Streptococcus mutans of saliva

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014091319131N1**
Registration date: **2015-04-28, 1394/02/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-04-28, 1394/02/08

Registrant information

Name

Elnaz Ghasemi

Name of organization / entity

Dental school,Islamic Azad University Isfahan(khorasgan)

Country

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Recruitment status

Recruitment complete

Funding source

Islamic Azad University of Isfahan(Khorasgan)

Expected recruitment start date

2014-04-04, 1393/01/15

Expected recruitment end date

2014-08-06, 1393/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effect of probiotic yogurt and gums containing xylitol on salivary mutans streptococcus reduction

Public title

comparison of the effect of probiotic yogurt and gums containing xylitol on salivary mutans streptococcus reduction

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:absence of any systemic disease ;having 105≤ CFU/ml saliva levels of MS Exclusion criteria: had not used antibiotics,cortons,antibacterial mouthwashes;topical fluride(except for fluoride toothpaste),within the 4-week prior to beginningof the

study;used daily probiotics and xylitol-containing chewing gums ;person with smoking and used contraceptive drugs.

Age
From **73 years** old to **58 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Islamic Azad Universityof Isfahan

Street address
Dental School,Islamic Azad Universityof Isfahan(khorasgan),Jey Street

City
Isfahan

Postal code

Approval date
2014-10-15, 1393/07/23

Ethics committee reference number
493040

Health conditions studied

1

Description of health condition studied
Amount of salivary streptococous mutans

ICD-10 code
A40.8

ICD-10 code description
Other streptococcal sepsis

Primary outcomes

1

Description
salivary mutans sterptococcus reduction

Timepoint
Befor study, immediately one day after complete use of probiotic yoghurt and Xylitol gum (3 weeks) and also 2 & 4 weeks after intervention

Method of measurement
First, saliva samples are cultured on specific medium (Mitis Salivarius Agar) using superficial culture method; eventually, the colonies are visually counted (based on the forming units of colonies in 1ml of saliva (CFU/ml))

Secondary outcomes

1

Description
reduction of dental caries

Timepoint
Before study and immediately one day after complete use of probiotic yoghurt and Xylitol gum (3weeks) and also 2 and 4 weeks after intervention

Method of measurement
ابتدا نمونه های بزاق روی محیط اختصاصی Mitis Salivarius Agar به روش کشت سطحی کشت داده خواهند شددر نهایت شمارش کلنی ها به روش چشمی انجام می شود(بر مبنای تعداد واحد تشکیل دهنده کلونی در1 میلی لیتربزاق CFU/ml).

Intervention groups

1

Description
Group 1: 200 cc probiotic yoghurt (Kaleh) daily,for 3 weeks, 10 min after dinner.

Category
Prevention

2

Description
Group 2: 3 times a day (after 3 meals) 2 pieces (1.86 gr Xylitol) at least for 5 min in a 3-week period Xylitol-containing chewing gum (ORION DR. XYLITOL)

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental School,Islamic Azad University of Isfahan(Khorasgan)

Full name of responsible person
Elnaz Ghasemi

Street address
Dental School, Islamic Azad University Isfahan(Khorasgan), Jey Street, Isfahan

City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dental School,Islamic Azad University of Isfahan(Khorasgan)
Full name of responsible person
Dr Vahid Esfahanian
Street address
Dental school,Islamic Azad Universityof Isfahan(Khorasgan),Jey street
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Dental School,Islamic Azad University of Isfahan(Khorasgan)
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Postgraduated Student,Pediatric Dentistery
Full name of responsible person
Elnaz Ghasemi
Position
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code

empty

Data Dictionary

empty