Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assessment the effect of sugar free chewing gum to reduce cariogenic microorganism

Protocol summary

Summary

Aim:the present study sought to compare the effects of chewing xylitol-containing gums and conventional gums on S. mutans in the saliva of subjects with moderate and poor oral hygiene. Design:This study adopt a crossover design. Two type of chewing gums (one containing 70% xylitol and approve by the Iranian Dental Association and another containing sucrose) were purchase. The participants are 32 individuals aged18-35 years old whose oral hygiene are categorize as moderate or poor based on caries-risk assessment table. Setting and conduct: Either All subjects were instruct to take three gums a day after main meals (breakfast, lunch, and dinner) and chew each gum for 15 minute. The two groups with moderate and poor oral hygiene (n = 16) were each divide into two groups of eight to receive either PK® gums or Xylitol gums during the first 10-day period. After a 10-day washout period, each group receive the other type of gums for another 10 days. Saliva samples were collected and tested before and after each stage. Salivary levels of S. mutans were measure at baseline, after the first and second phases of chewing gums, and after the washout period. The measurements are performed on blood agar and mitis salivarius bacitracin agar When the presence of S. mutans was confirmed, the number of S. mutans colonies forme on the blood agar medium was count. Pair wise comparisons are then use to analyze the collecte data. Participant including major: Individuals were not included if they have any systemic diseases, history of head and neck radiotherapy, or sensitivity to xylitol. Persons receiving any type of antibiotics are not included Intervention: using sugar free xylitol chewing gum and sugared gum in poor and moderate oral hygiene group. Main out come measure: Salivary levels of S. mutans were measure at baseline and after the first and second phases of chewing gums, and after the washout period. the number of s. mutans compared between poor and moderate oral hygiene group

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015093024274N1**
Registration date: **2015-12-21, 1394/09/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-21, 1394/09/30

Registrant information

Name

Elahe Afshari Esfidvajani

Name of organization / entity

Shahed univercity, Dental school

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Assessment the effect of sugar free chewing gum to reduce cariogenic microorganism

Public title
Effect of sugar free chewing gum on main caries induce microorganism

Purpose
Prevention

Inclusion/Exclusion criteria
Exclution criteria: Any systemic diseases; history of head and neck radiotherapy; or sensitivity to xylitol; Persons receiving any type of antibiotics were not included either

Age
From **18 years** old to **35 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahed university,dental school

Street address
Number 39, Italy St, Vesal St, Enghelab St

City
Tehran

Postal code
1417755351

Approval date
2014-07-06, 1393/04/15

Ethics committee reference number
41/205159

Health conditions studied

1

Description of health condition studied
Assessment the effect of chewing gum on salivary S. mutans count

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Streptococcus mutans count

Timepoint
Immediately befor start first 10 days intervention and immediately after finish first ten days period and immediatly after finish ten days wash out period and immediatly after finish second ten days intervention

Method of measurement
Microbiologic test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group a: Xylitol chewing gums (Orion Food Vina Co. Ltd, Vietnam) containing 70% xylitol, isomalt, Arabic gum, and calcium lactate were purchased from a gum wholesaler in Tehran . The gums were 1.5 g each and were approved by the Iranian Dental Association. All subjects were instructed to take three gums a day after main meals (breakfast, lunch, and dinner) and chew each gum for 15 minutes. for ten days period

Category
Prevention

2

Description
Intervention group b: PK® gums (1.6 g, Wrigley, India) containing sucrose, glucose, gum, mint extract, pigments, titanium dioxide, were also purchased. The chewing gums were packed in similar 30-gum packages and distributed among the participants. All subjects were instructed to take three gums a day after main meals (breakfast, lunch, and dinner) and chew each gum for 15 minutes.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahed university, faculty of dentistry

Full name of responsible person
Karami

Street address
Number 39, Italy St, Vesal St, Enghelab St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of dental school of Shahed university
Full name of responsible person
MIS Gharaje
Street address
Number 39, Italy St, Vesal St, Enghelab St
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of dental school of Shahed university
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
Shahed university, Faculty of dentistry
Full name of responsible person
Roza Haghgoo
Position
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Person responsible for updating data

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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