

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 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

+98 913 309 1663

Email address

mostajeran@med.mui.ac.ir

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

Exclusion 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 before start first 10 days intervention and immediately after finish first ten days period and immediately after finish ten days wash out period and immediately 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

City

Tehran

Web page address

Shahed.ac.ir

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

Shahed University, Dental school

Full name of responsible person

Roza Haghgoo

Position

Pedodontist

Other areas of specialty/work**Street address**

Number 39, Italy St, Vesal St, Enghelab St

City

Tehran

Postal code

1417755351

Phone

+98 21 8836 0461

Fax

+98 21 8836 0461

Email

haghgoodent@yahoo.com

Web page address**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

Pedodontist/Professor, Dept of Pediatric Dentistry, Dental School, Shahed University

Other areas of specialty/work**Street address**

Number 39, Italy St, Vesal St, Enghelab St

City

Tehran

Postal code

1417755351

Phone

+98 21 8836 0461

Fax

+98 21 8836 0461

Email

haghgoodent@yahoo.com

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

Shahed University, Dental school

Full name of responsible person

Elahe Afshari

Position

Resident, Dept of Pediatric Dentistry

Other areas of specialty/work**Street address**

Number 39, Italy St, Vesal St, Enghelab St

City

Tehran

Postal code**Phone**

+98 21 8836 0461

Fax

+98 21 8836 0461

Email

Elaheafshar59@gmail

Web page address**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