

# 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 aged 18-35 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

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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**

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

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Shahed.ac.ir

**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

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**City**

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**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

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**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*