Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of chewing Xylitol gum on saliva mutans streptococci in children

Protocol summary

Summary

Background and aim: Mutans streptococci are one the basic microorganisms that influence in dental caries process. Every year much money spends to treat and repair caries teeth. One of the methods to decrease saliva mutans is to chew xylitol gum to increase saliva rate and decrease the mutans streptococci rate in the mouth .This study is performed to determine the effect of xylitol gum on the saliva streptococci rate in children who have been admitted dental branch of Islami Azad Universiyt in 2013. Material and methods: This study is performed experimentally and is investigated 30 children in 10-12 years old who are admitted in pediatric and orthodontic departments of dental branch in Islamic Azad University. The cases had not any systemic disease and active caries cavities and periodontitis , they have not used any antibiotic medication and they are not regular users of gum (i.e. 4 pieces daily).They have not experienced orthodontic treatment and are not fluoride mouth wash users , Initially we will culture mutans streptococci in saliva samples of the cases. We ordered the culture results from minimum to maximum amount and randomly divide them in 3 groups of 10 .Group A: is given gum with xylitol, group B: is given gum base, group C: control group (has nothing to chew) after 30 days, the cases attended in saliva sampling process again. In this study the amount of saliva mutans streptococci at the first day and after 30 days is calculated and the changes will be analyzed by krus-kalvalis test. Also the decreasing mutans rate will be calculated by K2 .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013010111960N1**
Registration date: **2013-02-13, 1391/11/25**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-02-13, 1391/11/25

Registrant information

Name
Nasim Shafiezadeh
Name of organization / entity
Islamic Azad University, Dental branch
Country
Iran (Islamic Republic of)
Phone
+98 21 2256 4571
Email address
n_shafiezadeh@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

researchers

Expected recruitment start date

2013-01-09, 1391/10/20

Expected recruitment end date

2013-02-08, 1391/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of chewing Xylitol gum on saliva mutans streptococci in children

Public title

The effect of Xylitol gum

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: 10-12 year children; their parents have given informed consent; streptococcus mutans in saliva>10000, fasting from 2 hours before saliva sampling; being accessible for saliva sampling in 11 am. Exclusion Criteria: chewing gum usually (4 piece a day or more); using fluoride mouthwash or topical fluoride therapy or any kind of antibiotic therapy in last 3 months ; any systemic illness; any periodontal disorder; any obvious cavity in their teeth; using probiotic products in their usual diet; orthodontic therapy.

Age
From **10 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Islamic Azad University, Dental Branch

Street address
NO5 ,Niestan 10, Pasdaran

City
Tehran

Postal code

Approval date
2011-12-11, 1390/09/20

Ethics committee reference number
د/768/ب

Health conditions studied

1

Description of health condition studied
Dental caries

ICD-10 code
K02

ICD-10 code description
Dental caries

Primary outcomes

1

Description
Saliva mutans Streptococci

Timepoint
before and one mouth after

Method of measurement
Saliva mutans Streptococci is cultured on mitis salivaris agar and samples with more than 10,000 CFU are choosed

Secondary outcomes

empty

Intervention groups

1

Description
Intervention: chewing 1 piece Dr Xylitol chewing gum after each meal everyday (3 piece a day)

Category
Prevention

2

Description
Control1: chewing 1 piece gum base (saghez) after each meal (3 piece a day)

Category
Placebo

3

Description
Control 2: No intervention

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental Branch,Islamic Azad University

Full name of responsible person

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
personally
Full name of responsible person
Dr Nasim Shafiezadeh
Street address
Pediatric department,Dental Branch,Islamic Azad university
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
personally
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
Pediatric Dep.Dental Branch, Islamic Azad University
Full name of responsible person
Dr Nasim Shafiezadeh
Position
Assisstant Professor
Other areas of specialty/work
Street address
first floor, No5, Niestan 10, Pasdaran
City
Tehran
Postal code
Phone
+98 21225645713
Fax
Email
n_shafiezadeh@dentaliau.ac.ir ; nshafizad@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Assisstant Professor
Full name of responsible person
Dr Nasim Shafie zadeh
Position
Pediatric Dentist, DDS
Other areas of specialty/work
Street address
Dental Branch
City
Tehran
Postal code
Phone
+98 21 2256 4571
Fax
Email
n_shafiezadeh@dentaliau.ac.ir ; nshafizad@yahoo.com
Web page address

Person responsible for updating data

Contact

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