

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 University 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 kruskalwalis 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 Shafieezadeh

Name of organization / entity

Islamic Azad University, Dental branch

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 4571

Email address

n_shafieezadeh@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

ب/768/د

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 month 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 Shafieezadeh

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

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

Assistant Professor

Full name of responsible person

Dr Nasim Shafie zadeh

Position

Pediatric Dentist, DDS

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

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Pediatric Dep.Dental Branch, Islamic Azad University

Full name of responsible person

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Position

Assistant Professor

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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