

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

comparison of the effect of probiotic yogurt and gums containing xylitol on salivary mutans streptococcus reduction

Protocol summary

Summary

Objective of the study: a comparison between the impact of probiotic yoghurt and xylitol-containing chewing gum on the reduction of Streptococcus mutans of saliva. Study design: randomized clinical trial. Population: selected among the resident students in female dormitory of Islamic Azad University of khorasgan. Inclusion criteria: lack of any systemic diseases, having ≥ 150 forming units of Streptococcus mutans colony in 1 ml of saliva. Exclusion criteria: use of any types of antibiotics and medications containing corticosteroids and antibacterial mouthwash and topical Fluoride (except Fluoridated toothpaste) 4 weeks before study starts, regular use of probiotic products and Xylitol-containing gums, smoking and taking contraceptive drugs. Sample size: 50 participants. Interventions: participants are randomly divided to 2 groups; group 1 will have probiotic yoghurt and group 2 will have xylitol gum. Intervention time: 3 Weeks. Study implication: reducing Streptococcus mutans of saliva

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014091319131N1**

Registration date: **2015-04-28, 1394/02/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-04-28, 1394/02/08

Registrant information

Name

Elnaz Ghasemi

Name of organization / entity

Dental school, Islamic Azad University
Isfahan(khorasgan)

Country

Iran (Islamic Republic of)

Phone

+98 31 3535 4053

Email address

el.ghasemi@khuif.ac.ir

Recruitment status

Recruitment complete

Funding source

Islamic Azad University of Isfahan(Khorasgan)

Expected recruitment start date

2014-04-04, 1393/01/15

Expected recruitment end date

2014-08-06, 1393/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effect of probiotic yogurt and gums containing xylitol on salivary mutans streptococcus reduction

Public title

comparison of the effect of probiotic yogurt and gums containing xylitol on salivary mutans streptococcus reduction

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: absence of any systemic disease ;having $10^5 \leq$ CFU/ml saliva levels of MS Exclusion criteria: had not used antibiotics, corticosteroids, antibacterial mouthwashes; topical fluoride (except for fluoride toothpaste), within the 4-week prior to beginning of the

study;used daily probiotics and xylitol-containing chewing gums ;person with smoking and used contraceptive drugs.

Age

From **73 years** old to **58 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Azad University of Isfahan

Street address

Dental School, Islamic Azad University of Isfahan (Khorasgan), Jey Street

City

Isfahan

Postal code

Approval date

2014-10-15, 1393/07/23

Ethics committee reference number

493040

Health conditions studied

1

Description of health condition studied

Amount of salivary streptococcus mutans

ICD-10 code

A40.8

ICD-10 code description

Other streptococcal sepsis

Primary outcomes

1

Description

salivary mutans streptococcus reduction

Timepoint

Before study, immediately one day after complete use of probiotic yoghurt and Xylitol gum (3 weeks) and also 2 & 4 weeks after intervention

Method of measurement

First, saliva samples are cultured on specific medium (Mitis Salivarius Agar) using superficial culture method; eventually, the colonies are visually counted (based on the forming units of colonies in 1ml of saliva (CFU/ml))

Secondary outcomes

1

Description

reduction of dental caries

Timepoint

Before study and immediately one day after complete use of probiotic yoghurt and Xylitol gum (3 weeks) and also 2 and 4 weeks after intervention

Method of measurement

ابتدا نمونه های بزاق روی محیط اختصاصی Mitis Salivarius Agar به روش کشت سطحی کشت داده خواهند شد در نهایت شمارش کلنی ها به روش چشمی انجام می شود (بر مبنای تعداد واحد تشکیل دهنده CFU/ml) در 1 میلی لیتر بزاق

Intervention groups

1

Description

Group 1: 200 cc probiotic yoghurt (Kaleh) daily, for 3 weeks, 10 min after dinner.

Category

Prevention

2

Description

Group 2: 3 times a day (after 3 meals) 2 pieces (1.86 gr Xylitol) at least for 5 min in a 3-week period Xylitol-containing chewing gum (ORION DR. XYLITOL)

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School, Islamic Azad University of Isfahan (Khorasgan)

Full name of responsible person

Elnaz Ghasemi

Street address

Dental School, Islamic Azad University Isfahan (Khorasgan), Jey Street, Isfahan

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Dental School, Islamic Azad University of Isfahan (Khorasgan)

Full name of responsible person
Dr Vahid Esfahanian

Street address
Dental school, Islamic Azad University of Isfahan (Khorasgan), Jey street

City
Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Dental School, Islamic Azad University of Isfahan (Khorasgan)

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
Postgraduated Student, Pediatric Dentistry

Full name of responsible person
Elnaz Ghasemi

Position
Postgraduate of Pediatric Dentistry

Other areas of specialty/work

Street address
Dental School, Islamic Azad University of Isfahan (Khorasgan), Jey St

City
Isfahan

Postal code

Phone
+98 31 3535 4053

Fax

Email
ghasemi_elnaz_27@yahoo.com
El.ghasemi@khuisf.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University of Isfahan

Full name of responsible person
Elnaz Ghasemi

Position
Postgraduated Student, Pediatric Dentistry

Other areas of specialty/work

Street address
Dental School, Islamic Azad University of Isfahan (Khorasgan), Jey St

City
Isfahan

Postal code

Phone
+98 31 3535 4053

Fax

Email
ghasemi_elnaz_27@yahoo.com
El.ghasemi@khuisf.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University of Isfahan

Full name of responsible person
Elnaz Ghasemi

Position
Postgraduated Student, Pediatric Dentistry

Other areas of specialty/work

Street address
Islamic Azad University of Isfahan (Khorasgan), Jey Street

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Fax

Email
ghasemi_elnaz_27@yahoo.com
El.ghasemi@khuisf.ac.ir

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