

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Effect of Consumption of Probiotic Yoghurt on the Children's Salivary Cariogenic Microflora

Protocol summary

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Summary

The aim of this study is to examine whether or not short-term consumption of yogurt containing bifidobacteria will affect the salivary levels of mutans streptococci and lactobacilli in children. This is a double-blind, randomized, preventive and without placebo study. The study group contains 50 healthy Iranian children aged 6-12 years who will follow over 4 periods, during periods 2 and 4 (2 weeks each), they will ingest 200 g yogurt containing Bifidobacterium once daily or a control yogurt without viable bacteria. Periods 1 and 3 will be washout periods. Regular xylitol chewing gum consumers and subjects with systemic antibiotic or topical fluoride treatments within 4 weeks will not be included.

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-04-20, 1391/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201308871N1**

Registration date: **2012-02-26, 1390/12/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-02-26, 1390/12/07

Registrant information

Name

Nasim Seyfi

Name of organization / entity

Dental school, Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1654 1350

Email address

Scientific title

Effect of Consumption of Probiotic Yoghurt on the Children's Salivary Cariogenic Microflora

Public title

Effect of Consumption of Probiotic Yoghurt on the teeth caries

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Healthy children aged 6-12 years; Not using xylitol chewing gum and probiotic yoghurt.

Exclusion criteria: Children with systemic diseases; subjects with systemic antibiotic or topical fluoride treatments within 4 weeks.

Age

From **6 years** old to **12 years** old

Gender

Both

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)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences

Street address

7th floor, central building of Shiraz University of Medical Sciences, Zand st.

City

Shiraz

Postal code**Approval date**

2012-01-21, 1390/11/01

Ethics committee reference number

90-5915

Health conditions studied**1****Description of health condition studied**

Caries

ICD-10 code

K02

ICD-10 code description

dental caries

Primary outcomes**1****Description**

mutans streptococci

Timepoint

before, after 2, 4 & 6 weeks

Method of measurement

The counts of salivary mutans streptococci

2**Description**

lactobacilli

Timepoint

before, after 2, 4 & 6 weeks

Method of measurement

The counts of salivary lactobacilli

Secondary outcomes

empty

Intervention groups**1****Description**

Consumption of probiotic yogurt for study group. Daily intake is 200gr.

Category

Prevention

2**Description**

Consumption of usual yogurt for control group. Daily intake is 200gr.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shiraz Dental School

Full name of responsible person**Street address****City**

Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Hatam

Street address

7th floor, Central Building of Shiraz University of Medical Sciences, Zand st.

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Sciences

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**

Shiraz Dental School

Full name of responsible person

Nasim Seyfi

Position

Resident of pediatric dentistry

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

Dental School, GhomAbad St. Ghasroldasht St.

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Fax**Email**

nasimseyfi@gmail.com , seyfin@sums.ac.ir

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

Shiraz Dental School

Full name of responsible person

Nasim Seyfi

Position

Resident

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

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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