Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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.

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)

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Email address

seyfin@sums.ac.ir

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

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
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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