Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation the effect of probiotics drops on salivary Streptococcus mutans and lactobacilli in children 3 to 6 years old

Protocol summary

Summary

L. rhamnosus and L.ruteri and Bifid bacterium infantis on salivary Lactobacillus and Streptococcus mutans. Design: double-blind randomized placebo-controlled trial with two parallel groups. The inclusion criteria: 3-6 years old children; have no systemic diseases and with good oral health; Any product containing probiotics and xylitol are not used within 4 weeks ago; had not receive systemic antibiotics and topical fluoride treatment for 4 weeks ago. The exclusion criteria: consume of probiotics, xylitol and systemic antibiotic medication or topical fluoride treatment during the study. Intervention: randomly 26 children will receive placebo drops (control group) and 26 children will receive probiotic drops (experimental group). The parents were asked to give children 5 drops every night before go to bed and refrain children from brushing and eating/drinking for at least one hours after for 2 weeks. Saliva sampling: Before and after the intervention at 7:30 to 8:30 a.m. unstimulated saliva will be collected in a sterile container. No tooth brushing or other tooth-cleaning methods and eating/drinking were allowed before sampling. Immediately samples will be sent to the laboratory for culture and colonies counted. Study Outcome: change level of salivary Lactobacillus and Streptococcus mutan

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014120320202N1**
Registration date: **2015-07-14, 1394/04/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-07-14, 1394/04/23

Registrant information

Name
Leila Talebian
Name of organization / entity
Isfahan Universiy of Medical Sciences, School of Dental Medicine
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2015-02-04, 1393/11/15

Expected recruitment end date

2015-03-19, 1393/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of probiotics drops on salivary Streptococcus mutans and lactobacilli in children 3 to 6 years old

Public title

Evaluation the effect of probiotics drops on saliva bacteria causing caries in children 3 to 6 years old

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria: 3-6 years old children ; no

systemic diseases; with good oral health; Any product containing probiotics and xylitol are not used within 4 weeks ago and had not receive systemic antibiotics and topical fluoride treatment for 4 weeks ago.The exclusion criteria: consume of probiotics, xylitol and systemic antibiotic medication or topical fluoride treatment

Age
From **3 years** old to **6 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Hezar jerib St., Isfahan

City
Isfahan

Postal code
8174673461

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
393875

Health conditions studied

1

Description of health condition studied
Dental caries

ICD-10 code
k02.9

ICD-10 code description
Dental caries, unspecified

Primary outcomes

1

Description
The number of Lactobacilli in saliva

Timepoint
The start of the study, day the fourteenth

Method of measurement
Microbial culture

2

Description
The number of Streptococcus mutans in saliva

Timepoint
The start of the study, day the fourteenth

Method of measurement
Microbial culture

Secondary outcomes

empty

Intervention groups

1

Description
pedilac placebo drop ,2 weeks,every night,befor sleep,5 drops

Category
Placebo

2

Description
pedilac probiotic drop ,2 weeks,every night,befor sleep,5 drops

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Pediatrics, School of Dentistry, Isfahan University of Medical Sciences

Full name of responsible person
Leila Talebian

Street address
School of Dentistry, Isfahan University of Medical Sciences, Hezarjarib St., Isfahan, Iran

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person
Dr Mahdi Nematbakhsh

Street address
hezarjarib st, Isfahan

City
Isfahan

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor for research, Isfahan 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
Isfahan Dental Medical School

Full name of responsible person
Dr Maryam Tehrani

Position
Professor in the Department of Pediatric Dentistry; Professional Doctor of Pediatric Dentistry

Other areas of specialty/work

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General Dentist; Assistant Professor of Pediatric Dentistry

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Person responsible for updating data

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General Dentist; Assistant Professor of Pediatric Dentistry

Other areas of specialty/work

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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