

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 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 University of Medical Sciences, School of Dental Medicine

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 2891

Email address

leila.talebian@dnt.mui.ac.ir

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**Street address**

Hezar jerib St., Isfahan

City

Isfahan

Postal code

36687080

Phone

+98 31 3972 2891

Fax

+98 31 3668 7080

Email

leila.talebiani@dnt.mui.ac.ir

Web page address

www.dnt.mui.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Isfahan Dental Medical School

Full name of responsible person

Leila.talebian

Position

General Dentist; Assistant Professor of Pediatric Dentistry

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

Hezar jerib St., Isfahan

City

Isfahan

Postal code

8174673461

Phone

+98 31 3792 2871

Fax

+98 36687080

Email

leila.talebian@yahoo.com Leila.talebiana@dnt.mui.ac.ir

Web page address

www.dnt.mui.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

School of Dental Medicine

Full name of responsible person

Leila Talebian

Position

General Dentist; Assistant Professor of Pediatric Dentistry

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

Hezar jerib st., Isfahan

City

Isfahan

Postal code

8174673461

Phone

+98 31 3792 2891

Fax

+98 31 3668 7080

Email

leila.talebiana@dnt.mui.ac.ir

Web page address

www.dnt.mui.ac.ir

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