

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Investigating the effect of daily consumption of probiotic milk and normal milk on the rate of caries of primary teeth (dmft) buffer status, pH, and the amount of Streptococcus mutans in the saliva of 3-6 years old children. A clinical trial

Protocol summary

Study aim

The effect of daily consumption of probiotic and regular milk on the rate of dental caries and Streptococcus mutans, and the buffering status and pH in children's saliva

Design

A phase 3 clinical trial that is randomized. 24 patients will be randomly assigned to two intervention and control groups.

Settings and conduct

This study will be conducted to investigate the preventive effects of prebiotic products on dental caries in children in Zanjan. children will be randomly assigned to two intervention and control groups. In the control group, they will receive non-probiotic milk, in the intervention group, a package containing probiotic powder along with milk. Saliva samples and caries index of the subjects will be measured at the beginning, 3, 6, and 12 months after the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy children who consume milk daily, without a history of systemic diseases or allergic reactions, availability to participate in the 6-month follow-up, consent to participate in the study. Exclusion criteria: Patients with a history of severe medical illness or allergic reactions, people who consume more or less than the recommended amount of milk.

Intervention groups

The intervention group includes children whose parents breastfeed them according to the minister's instructions. Parents will be instructed to prepare the milk as follows: A quarter teaspoon of probiotic powder from the L. paracasei SD1 probiotic sachet (fssai, KAN phytochemicalsal Pvt, India) will be added to 200 ml of milk (200 ml milks available in the market will be selected) to obtain a final concentration of 107 CFU/mL

for each use in the probiotic group. Due to ethical considerations, it is not possible to add another powder as a placebo in the control group.

Main outcome variables

caries index(dmft), pH level, Streptococcus mutans bacteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210718051926N2**

Registration date: **2025-07-28, 1404/05/06**

Registration timing: **registered_while_recruiting**

Last update: **2025-07-28, 1404/05/06**

Update count: **0**

Registration date

2025-07-28, 1404/05/06

Registrant information

Name

bahareh nazemi salman

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 24 3341 2597

Email address

dr.b.nazemi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-23, 1404/05/01
Expected recruitment end date
 2025-12-21, 1404/09/30
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Investigating the effect of daily consumption of probiotic milk and normal milk on the rate of caries of primary teeth (dmft) buffer status, pH, and the amount of Streptococcus mutans in the saliva of 3-6 years old children. A clinical trial

Public title
 effect of daily consumption of probiotic milk and normal milk on the rate of caries of primary teeth

Purpose
 Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Healthy children who drink milk daily, No history of systemic diseases or allergic reactions Availability to participate in the 6-month follow-up, Consent to participate in the study
Exclusion criteria:
 Patients with a history of severe medical illness or allergic reaction People who consume more or less than the recommended amount of milk.

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

Gender
 Both

Phase
 3

Groups that have been masked
No information

Sample size
 Target sample size: **24**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Children will be randomly assigned to two intervention and control groups. The method of assigning children to the two groups will be as follows: after meeting the study entry criteria, a number will be randomly generated by the Random Generator software (available online). If the number obtained is even, the child will be assigned to the intervention group, and if it is odd, the child will be assigned to the control group.

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

Ethics Committee of Zanjan University of Medical Sciences

Street address

mahdavi street

City

zanjan

Province

Zanjan

Postal code

4513956184

Approval date

2025-03-04, 1403/12/14

Ethics committee reference number

IR.ZUMS.REC.1403.327

Health conditions studied

1

Description of health condition studied

k00

ICD-10 code

k00

ICD-10 code description

tooth

Primary outcomes

1

Description

caries of primary teeth

Timepoint

Start of the study - Three months after the study - Six months after the study - Twelve months after the study

Method of measurement

DMFT decay index, which indicates the status of decayed teeth, teeth extracted due to decay, and teeth filled due to decay.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:One-fourth tablespoon of probiotic powder from the L. paracasei SD1 probiotic sachet (fssai, KAN phytochemicals Pvt, India) will be added to 200 mL

of milk (200 mL milks available in the market will be selected) to obtain a final concentration of 107 CFU/mL for each administration in the probiotic group.

Category

Other

2

Description

Control group: Children who will only receive regular milk(Routine milk powder).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabesam Children's Dental Clinic

Full name of responsible person

dr Bahareh Nazemi Salman

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<https://medicalnet.ir/Clinic/Type/View/ID/2397/%DA%A9%D9%84%DB%8C%D9%86%DB%8C%DA%A9-%D8%AA%D8%AE%D8%B5%D8%B5%DB%8C-%D8%AF%D9%86%D8%AF%D8%A7%D9%86%D9%B E%D8%B2%D8%B4%DA%A9%DB%8C-%D8%AA%D8%A8%D8%B3%D9%85>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

bahareh nazemi salman

Position

associated proffesor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

For those interested in research and those who plan to continue this research topic, the information they need will be sent to them after they submit their request. All data that will be entered into SPSS software can be shared after removing the names of the individuals.

When the data will become available and for how long

After the article is published and all information and analysis are extracted, it will be stated in the article that the responsible author will send the information to those interested if they receive an email.

To whom data/document is available

People interested in the results of this research topic in industry and academia

Under which criteria data/document could be used

There will be no restrictions on performing various analyses on this data. Email of the corresponding author that will be mentioned in the article dr Bahareh Nazemi Salman dr.b.nazemi@gmail.com

From where data/document is obtainable

Email of the corresponding author that will be mentioned in the article dr Bahareh Nazemi Salman dr.b.nazemi@gmail.com

What processes are involved for a request to access data/document

After receiving the email, the responsible author will make the necessary correspondence and send the file if necessary. Email of the corresponding author that will be mentioned in the article dr Bahareh Nazemi Salman dr.b.nazemi@gmail.com

Comments