# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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
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**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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## 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 updating data

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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**