# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## The effect of Kidi Lact on salivary streptococcus mutans in 8-12 years old children

### Protocol summary

**Study aim**
Determination of teeth health by decreasing Mutans streptococcus in saliva

**Design**
Randomized cross- over double-blinded clinical trial

**Settings and conduct**
30 healthy children ages 8 to 12 from two round-the-clock centers in Kerman, as volunteers, enter this study with informed consent. Stage One: The volunteers are asked to take no probiotic product for a week. Then non-stimulated saliva are taken for one minute from them at specific time before breakfast. The saliva samples are sent to the laboratory for checking the count of streptococcus. Then, the volunteers are divided into two groups randomly. In the second phase, the intervention group mouthwash solution of 1 gram sachet Kidi-Lact in 50 cc water and control group mouthwash placebo daily for 2 weeks for 1 minute, then non-stimulated saliva samples from the subjects will take .In the third stage, people in the study have a regular diet for one month, then again, people do not use any probiotic product for a week and their non-stimulated saliva samples are collected. In the fourth stage, the subjects in the two groups use a 1 gram of Kidi-Lact or placebo solution daily for 2 weeks, in such a way that Kidi Lact is given to the group that consumed the placebo in the previous step and vice versa. After two weeks, a sample of unstimulated saliva is collected and sent to the laboratory

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Children 8-12 years old; Physical and mental health; Daily brushing habit; Exclusion criteria: uncooperative patient; Use of Antibiotic one month prior to research; Use of mouthwash, fluoride gel and gum containing Xylitol one month prior to research; Having untreated decayed teeth

**Intervention groups**
Intervention group: participant who receive probiotic product( Kidi-Lact) Control group: participant who receive placebo

**Main outcome variables**
Mutans streptococcus count in saliva

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20161007030193N2**
Registration date: **2018-05-12, 1397/02/22**
Registration timing: **retrospective**

Last update: **2018-05-12, 1397/02/22**
Update count: **0**

**Registration date**
2018-05-12, 1397/02/22

**Registrant information**

**Name**
Iman Parisay

**Name of organization / entity**
Mashhad University of Medical Sciences-Mashhad Dental Faculty

**Country**
Iran (Islamic Republic of)

**Phone**
+98 51 3608 6977

**Email address**
parisayi@mums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-02-20, 1396/12/01

**Expected recruitment end date**
2018-03-17, 1396/12/26

**Actual recruitment start date**

2018-02-20, 1396/12/01

**Actual recruitment end date**

2018-03-17, 1396/12/26

**Trial completion date**

empty

**Scientific title**

The effect of Kidi Lact on salivary streptococcus mutans in 8-12 years old children

**Public title**

The effect of Kidi Lact on salivary streptococcus mutans in 8-12 years old children

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Physical and mental health Daily brushing habit 8-12 year old children

**Exclusion criteria:**

Uncooperative patient Use of Antibiotic one month prior to research Use of mouthwash,fluoride gel and gum containing Xylitol one month prior to research Having untreated decayed teeth

**Age**

From **8 years** old to **12 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **30**

Actual sample size reached: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study the participants divided into two groups by simple randomization method by use of random numbers table

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study all participant will receive Kidi-Lact and placebo in similar packages ,so they are blinds in the study .The operator who gets the samples and the person who evaluates the samples for microbial assess are blind too,because they have no idea about the group to which the person or the sample belongs.

**Placebo**

Used

**Assignment**

Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

**Street address**

Mashhad Dental Faculty, Vakil Abbad Blvd

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91735

**Approval date**

2017-07-12, 1396/04/21

**Ethics committee reference number**

IR.mums.sd.REC.1394.265

## Health conditions studied

### 1

**Description of health condition studied**

Saliva Streptococcus mutans count

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Saliva streptococcus mutans

**Timepoint**

base line,14,37,51 day

**Method of measurement**

counting streptococcus mutans in culture media under microscope

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Kidi Lact probiotic solution is mouth washed for 1 minute daily for 2 weeks

**Category**

Prevention

### 2

**Description**

Control group: placebo solution is mouth washed for 1 minute daily for 2 weeks

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Ashiyaneh ali charity
**Full name of responsible person**
Dr. Hamid reza Poureslami
**Street address**
No.16, Hojaj Blvd., Ashiyaneh ali charity
**City**
Kerman
**Province**
Kerman
**Postal code**
7618759666
**Phone**
+98 34 3261 7952
**Fax**
+98 34 3247 6644
**Email**
ashiyaneh_ali@yahoo.com
**Web page address**

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Vice chancellor for Research of Mashhad University of Medical Sciences
**Full name of responsible person**
Dr.Mohsen Tafaghodi
**Street address**
Vice chancellor for research, Mashhad University of Medical Sciences, Daneshgah Street
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
91778-99191
**Phone**
+98 51 1882 3255
**Email**
tafaghodim@mums.ac.ir

**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Vice chancellor for research, Mashhad 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**
Mashhad University of Medical Sciences
**Full name of responsible person**
Iman Parisay
**Position**
Associate professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Dentistry
**Street address**
Mashhad Dental Faculty, Vakil Abbad Blvd.
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
91735
**Phone**
+98 51 3608 6977
**Fax**
+98 51 3882 9500
**Email**
parisayi@mums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Iman Parisay
**Position**
Associate professor
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## Person responsible for updating data

**Contact**

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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**
Data are available among corresponding author
**When the data will become available and for how long**
After publication of the article
**To whom data/document is available**
Every one who needs for scientific aims such as researchers who work on systematic review projects
**Under which criteria data/document could be used**
For research aims by formal request
**From where data/document is obtainable**
Contact with corresponding author by e-mail address
**What processes are involved for a request to access data/document**
After discussion the authors decide to accept or reject the request
**Comments**