

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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

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91778-99191

Phone

+98 51 1882 3255

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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

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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