

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Assessment the Effect of Cheese and Curd Consumption on Salivary pH and Calcium in Preschool Children

Protocol summary

Determining changes in pH and calcium level of saliva

Study aim

Determining the Salivary pH and Calcium Levels After Eating Cheese and Curd in Children Aged 4-6 Years.

Design

Clinical trial. With two parallel groups of 15 people, double-blind, randomized. Phase 3 on 30 patients. The coin toss method will be used for randomization.

Settings and conduct

In the pediatric department of the Faculty of Dentistry, first one of the dairy compounds (cheese or curd) is given to children, and the saliva sample is collected in three stages and sent to the laboratory to measure the pH and calcium level of the saliva. The The laboratory technician and Statistics specialist are blinded

Participants/Inclusion and exclusion criteria

Children Aged 4 to 6 Years Who Are Systemically Healthy are Included in the Study. Children Who Use Orthodontic Appliances, or are Allergic to Dairy Ingredients, or Who do not Cooperate Properly to Conduct the Study, Will not be Included.

Intervention groups

Intervention groups1 and 2: In the children of the first and second group (15 people in every group), complete oral prophylaxis with a rubber cap will be done in the clinic and the mouth will be washed with plain water. Then, non-stimulating children's saliva samples are collected. In this way, children are asked to empty their saliva into disposable plastic coded containers with lids. The collected samples are taken to the laboratory to measure the pH and calcium of the saliva. Then all the children in the first and second group are given 50 grams of curd and 50 grams of chees to chew and roll it for three minutes and then swallow it. After that, the mouth will be washed with plain water and a non-stimulating saliva sample (5 cc) will be collected immediately after consumption and 30 minutes later, and will be sent to the laboratory to measure the calcium concentration and pH of the saliva.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171020036896N10**

Registration date: **2023-09-26, 1402/07/04**

Registration timing: **prospective**

Last update: **2023-09-26, 1402/07/04**

Update count: **0**

Registration date

2023-09-26, 1402/07/04

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 32119023

Email address

sajadi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-12, 1402/07/20

Expected recruitment end date

2024-01-10, 1402/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the Effect of Cheese and Curd Consumption on Salivary pH and Calcium in Preschool Children

Public title

Assessment the Effect of Cheese and Curd on Salivary pH and Calcium

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Children with 4 to 6 Years-Old Absence of Systemic Disease Appropriate Cooperation to Conduct the Study

Exclusion criteria:

Using Orthodontic Appliances Taking Antibiotics within Two Weeks Before the Start of the Study Having Extensive Restorations and Permanent or Temporary Restorations Containing Glass Ionomer Having an Allergy to Dairy Ingredients

Age

From **4 years** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this Study, the Simple Randomization Method (Flip the Coin) will be Used. In Such a Way that One of the Study Groups will be Considered as Heads and the Other Group will be Considered as Tails. Then the Same Number of Coins will be Thrown Based on the Sample Size. Finally, to Prevent Disclosure of Random Sequencing, the Allocation Concealment will be Used.

Blinding (investigator's opinion)

Double blinded

Blinding description

The Biochemist in the Laboratory does not Know the Type of Compound Used in Children. The Statistics Consultant is also not Aware of the Type of Combination Used.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Kerman University of Medical Sciences

Street address

Ebn Sina Avenue , Jahad Blvd ,

City

Kerman

Province

Kerman

Postal code

7618759689

Approval date

2022-11-07, 1401/08/16

Ethics committee reference number

IR.KMU.REC.1401.370

Health conditions studied

1

Description of health condition studied

Salivary pH and Calcium

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Salivary pH

Timepoint

Before, Immediately after and Half an Hour after Eating the Dairy Composition

Method of measurement

pH of saliva is Measured by pH Meter

2

Description

Salivary Calcium

Timepoint

Before, Immediately after and Half an Hour after Eating the Dairy Composition

Method of measurement

Calcium Concentration of Saliva is Measured by Colorimetric Method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: In the children of the first group (15 people), complete oral prophylaxis with a rubber cap will

be done in the clinic and the mouth will be washed with plain water. Then, non-stimulating children's saliva samples are collected. In this way, children are asked to empty their saliva into disposable plastic coded containers with lids. The collected samples are taken to the laboratory to measure the pH and calcium of the saliva. Then all the children in the first group are given 50 grams of curd to chew and roll it for three minutes and then swallow it. After that, the mouth will be washed with plain water and a non-stimulating saliva sample (5 cc) will be collected immediately after consumption and 30 minutes later, and will be sent to the laboratory to measure the calcium concentration and pH of the saliva.

Category

Prevention

2

Description

Intervention group 2: In the children of the second group (15 people), complete oral prophylaxis with a rubber cap will be done in the clinic and the mouth will be washed with plain water. Then, non-stimulating children's saliva samples are collected. In this way, children are asked to empty their saliva into disposable plastic coded containers with lids. The collected samples are taken to the laboratory to measure the pH and calcium of the saliva. Then all the children in the second group are given 50 grams of cheese to chew and roll it for three minutes and then swallow it. After that, the mouth will be washed with plain water and a non-stimulating saliva sample (5 cc) will be collected immediately after consumption and 30 minutes later, and will be sent to the laboratory to measure the calcium concentration and pH of the saliva.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry

Full name of responsible person

Fatemeh Sadat Sajadi

Street address

Shafa Ave

City

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Province

Kerman

Postal code

7618759689

Phone

+98 34 3211 8074

Email

fsajadi1234@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr.Abedin Iranpour

Street address

Shafa Ave.,

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7618759689

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Email

fsajadi1234@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Sajadi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

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Phone

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Sajadi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Sajadi

Position

Associate professor

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available