Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of salivary pH changes in children aged 6 to 12 following the use of fruit , plain and probiotic yogurt

Protocol summary

Study aim

Comparison of salivary pH changes in children aged 6 to 12 following the use of fruit , plain and probiotic yogurt

Design

clinical trial, Randomised, Single blinded, Sample size: 51, Number of people in each group: 17

Settings and conduct

Participants will be randomly divided into 3 groups of 17(A,B,C). In the day of experiment, an unstimulated saliva sample will be taken from each participant one hour after breakfast and then 10cc of selected yogurt is given to each participant and after 10 minutes another saliva sample is taken. The pH of both samples is calculated for participant by a pH meter, and the difference in these two values is considered as the pH change. The result will be reported (percent), mean ± SD-bearing for quantitative and qualitative variable. To compare the pH in and between the studied groups, the pair t-test and the analysis of Covariance(ANCOVA) will be used. To analyze the data, SPSS 17 will be used. The probability of less than 0.05 as a significant level will be considered.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.Obtaining parental consent to participate in the study 2.In the age group of 6-12 years 3.With good cooperation 4.Without systemic disease 5.No consumption any medicine 6.No orthodontic or prosthetic appliance in mouth 7.Symptom free such as toothache, etc Exclusion criteria: 1.Diagnosed with dry mouth 2.Allergy to yogurt or milk protein 3.With pathological lesions 4.With previous history of antibiotic therapy from 2 weeks ago

Intervention groups

1. One hour after breakfast, intervention with consumption of 10 cc fruit yogurt (peach) will be done. 2. One hour after breakfast, intervention with consumption of 10 cc plain yogurt will be done.(control group) 3. One hour after breakfast, intervention with consumption of 10 cc probiotic yogurt will be done.

Main outcome variables

salivary pH

General information

Reason for update

record actual recruitment start and end date and record trial completion date

Acronym

IRCT registration information

IRCT registration number: **IRCT20200411047018N1**
Registration date: **2020-04-22, 1399/02/03**
Registration timing: **prospective**

Last update: **2020-07-04, 1399/04/14**
Update count: **1**

Registration date

2020-04-22, 1399/02/03

Registrant information

Name
Azin Sohrabi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 41 3332 2938
Email address
azin.sohrabi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-07-15, 1399/04/25

Actual recruitment start date

2020-06-07, 1399/03/18

Actual recruitment end date
2020-06-24, 1399/04/04
Trial completion date
2020-06-24, 1399/04/04

Scientific title
Comparison of salivary pH changes in children aged 6 to 12 following the use of fruit , plain and probiotic yogurt

Public title
Comparison of salivary pH changes in children aged 6 to 12 following the use of fruit , plain and probiotic yogurt
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Obtaining parental consent to participate in the study In the age group of 6-12 years With good cooperation Without systemic disease No consumption any medicine No orthodontic or prosthetic appliance in mouth Symptom free such as toothache, etc
Exclusion criteria:
Diagnosed with dry mouth Allergy to yogurt or milk protein With pathological lesions With previous history of antibiotic therapy from 2 weeks ago
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **51**
Actual sample size reached: **51**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization, individual, roll of a die (number 1,2 for group A, number 3,4 for group B, number 5,6 for group C)
Blinding (investigator's opinion)
Single blinded
Blinding description
The analyzer does not know the type of consumable and the consumable is marked with the codes A,B,C.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences , Golgasht Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
-
Approval date
2020-02-17, 1398/11/28
Ethics committee reference number
IR.TBZMED.REC.1398.1254

Health conditions studied

1

Description of health condition studied
Dental caries
ICD-10 code
K02
ICD-10 code description
Dental caries

Primary outcomes

1

Description
Salivary pH
Timepoint
Before the intervention and 10 minutes after the intervention
Method of measurement
pH meter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One hour after breakfast, each person is given 10 cc of fruit yogurt (peach, all three of which are the products of a yogurt company) and should be kept in the mouth for 2 minutes.
Category
Prevention

2

Description
Control group: One hour after breakfast, each person is

given 10 cc of plain yogurt (all three of which are the products of a yogurt company) and should be kept in the mouth for 2 minutes.

Category

Prevention

3

Description

Intervention group: One hour after breakfast, each person is given 10 cc of probiotic yogurt (all three of which are the products of a yogurt company) and should be kept in the mouth for 2 minutes.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz dental faculty

Full name of responsible person

Azin Sohrabi

Street address

Pediatric dentistry department, Dental Faculty, Golgasht Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

-

Phone

+98 41 3355 9659

Email

azin.sohrabi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Assistance of Research and Technology of Tabriz School of Dentistry

Full name of responsible person

Mozhgan Kachuei

Street address

Dental Faculty, Golgasht Ave.

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Tabriz

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East Azarbaijan

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Phone

+98 41 3334 0310

Email

kachoei@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Assistance of Research and Technology of Tabriz School of Dentistry

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

Tabriz University of Medical Sciences

Full name of responsible person

Azin sohrabi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Pediatric dentistry department, Dental Faculty, Golgasht Ave.

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East Azarbaijan

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Azin sohrabi

Position

assistant professor

Latest degree

Specialist

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Person responsible for updating data

Contact

Name of organization / entity

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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