

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 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 \pm 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

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Pediatric dentistry department, Dental Faculty, Golgasht Ave.

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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

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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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Azin Sohrabi
Position
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Latest degree
Specialist
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