

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of salivary PH changes after different fruits intake

Protocol summary

Study aim

Determination and compare salivary pH changes iafter consuming fruit

Design

Clinical trial with control group, with parallel groups, randomized, phase 2 on 115 patients(23 people in each group)permutation randomization method was used.

Settings and conduct

The study is conducted on dental students in Zahedan. Prophylaxis takes place on the first day. Sampling is done at 10-12 in the morning.Saliva sampling for different fruits is done at different times (in the same group). The minimum time interval between consuming two fruits is 1 day. First, a baseline saliva sample is prepared (the study group is considered as a control on the first day), then the consumption of fruits starts in the following days. On the second day, the unstimulated saliva is collected in a sitting position before consuming the fruit within 3 minutes and every 60 seconds using the spitting method, and half an hour later re-sampling 1, 5 and 10 minutes after consuming a 200 gram fruit in Separate tubes are made (the test tubes are numbered from 1-4 for each person) and they are transferred to the lab to evaluate the pH of saliva. Then, in the following days, sampling is done for other fruits in the same way.

Participants/Inclusion and exclusion criteria

Dental students 20 to 30 years old Exit criteria: Suffering from systemic diseases, history of drug use in the last 3 months, acute or chronic dental or periodontal infection and abscess, salivary gland disorders such as Sjogren's, stone, infection, neoplasm, history of radiotherapy, smoking and drug use, pregnancy and use of internal devices Mouth like orthodontic plaque Inclusion criteria: MFT < 3 (dental status) Age 20 to 30 years

Intervention groups

The intervention group includes the group that consumes apples, oranges, kiwi and pomegranate and the group that does not consume fruits

Main outcome variables

Acidity of saliva

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191012045067N8**

Registration date: **2023-05-10, 1402/02/20**

Registration timing: **prospective**

Last update: **2023-05-10, 1402/02/20**

Update count: **0**

Registration date

2023-05-10, 1402/02/20

Registrant information

Name

masoomeh shirzaiy

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3321 1135

Email address

shirzaiy@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-06-25, 1402/04/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of salivary PH changes after different fruits

intake

Public title

Investigation of salivary PH changes after different fruits intake

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

No systemic disease, no history of drug use in the past 3 months, no infection or acute or chronic dental or periodontal abscesses no salivary gland disorders such as, stones, infection, neoplasms, no intravenous radiotherapy, ,no history of smoking and drug use no history of Oral plaque use such as orthodontic plaque, no oral lesions no periodontal problems

Exclusion criteria:

Reluctance to cooperate Age over 30 years

Age

From **20 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **115**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of students to 5 groups is done by permuted block stratified randomization method. In this way, first the volunteer and eligible students are classified according to age and gender in the order of entry. Then, among all the possible states of permutations, they are randomly assigned to the desired group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University of Medical Sciences

Street address

Dental school, Azadegan street

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

98176996930

Approval date

2023-01-08, 1401/10/18

Ethics committee reference number

IR.ZAUMS.REC.1402.022

Health conditions studied

1

Description of health condition studied

The quality of saliva and caries

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

En salivary PH rate

Timepoint

Before use, 1.5 and 10 minutes after use

Method of measurement

ph-meter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group 1: In this group, the participant consumes a medium apple for 5 minutes

Category

Other

2

Description

Intervention group: Intervention group 2: In this group, the participant consumes a medium kiwi for 5 minutes

Category

Other

3

Description

Intervention group 3: In this group, the participant consumes a medium pomegranate for 5 minutes

Category

Other

4

Description

Intervention group 4: In this group, the participant consumes a medium orange for 5 minutes

Category

Other

5

Description

Control group: In this group, the participant does not consume fruit

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan dental school

Full name of responsible person

Masoomeh Shirzaiy

Street address

Dental school, Azadegan street

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9817699693

Phone

+98 54 3344 1814

Email

shirzaiy@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Somaye Ansari Moghaddam

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Dental school, Azadegan street

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ma_sarani2000@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

No

Title of funding source

-

Proportion provided by this source

1

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Masoomeh Shirzaiy

Position

Faculty

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Masoomeh Shirzaiy

Position

Faculty

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Masoomeh Shirzaiy
Position
Faculty member
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Dental school, Azadegan street
City
Zahedan
Province
Sistan-va-Balouchestan

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available