Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 pomegranatefor 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
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
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
Street address
Dental school, Azadegan street
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9817699693v
Phone
+98 54 3344 1824
Email
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
Masoome Shirzaiy
Position
Faculty
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Dental school, Azadegan street
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9817699693
Phone
+98 54 3341 4005
Email
shirzaiy@gmail.com

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
Dentistry
Street address
Dental school, Azadegan street
City
Zahedan
Province
Sistan-va-Balouchestan

Postal code
9817699693
Phone
+98 54 3344 1824
Email
shirzaiy@gmail.com

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
Postal code
9817699693
Phone
+98 54 3344 1824
Email
shirzaiy@gmail.com

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