

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of two types of flavored chewing gum (Action and Biodent) on salivary pH and volume

Protocol summary

The Effect of action and biodent flavored gum consumption on the dental caries decreasing-salivary ph

Study aim

assessment the effect of two types of flavored chewing gum (Action and Biodent) on salivary pH and volume

Design

Clinical trial with control group, double blind, randomized, phase 2, sample size 60

Settings and conduct

This simple double blind (analyzer, volunteer)clinical trial study performed on 20-30 years-old Zahedan dental students. From study subjects asked to refrain from eating and drinking 90 minutes before the test. The minimum time interval between Action gum and Biodent should be 1 day. Before consuming , unstimulated saliva is collected within 3 minutes and every 60 seconds, one hour before and after consumption, half an hour later, re-sampling is done 1, 5 and 10 minutes after consuming Biodent flavored gum in separate tubes, and pH of saliva is measured with a pH meter. Then the consumption of Biodent chewing gum is stopped and on the second day non-irritating saliva is collected before consumption and one hour after consumption of flavored action chewing gum, within 3 minutes and every 60 seconds and half an hour later re-sampling 1, 5 and 10 minutes after consuming a piece of gum, saliva is measured in separate tubes. The resulting information is recorded

Participants/Inclusion and exclusion criteria

dental students aged 20 - 30 year old Inclusion criteria : No systemic disease, no history of drug use in the past 3 months No infection or acute or chronic dental or periodontal abscess No salivary gland disorders such as sjogren, stones, infection, neoplasm No histories of radiotherapy, tobacco use and drugs Do not use intraoral devices such as orthodontic plaque No oral lesions and no periodontal problems Exclusion criteria: uncooperate the age under 20 and over 30 years

Intervention groups

action gum consumer group and biodent gum consumer group

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191012045067N7**

Registration date: **2023-05-09, 1402/02/19**

Registration timing: **prospective**

Last update: **2023-05-09, 1402/02/19**

Update count: **0**

Registration date

2023-05-09, 1402/02/19

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

2023-05-24, 1402/03/03

Expected recruitment end date

2023-07-27, 1402/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of two types of flavored chewing gum (Action and Biodent) on salivary pH and volume

Public title

Investigating the effect of two types of flavored chewing gum (Action and Biodent) on salivary pH and volume

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:

Unwillingness to cooperate Age over 30 years

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of participants to two groups is done by simple randomization method. In this way, After referring people, one of them will be assigned to intervention group 1 and the other to intervention group 2

Blinding (investigator's opinion)

Double blinded

Blinding description

he participant and analyzer do not know the type of consumables and the consumables are numbered as 1 , 2.The substance is given to the participant in a same cover with a coding and the analyzer records information only based on the desired code

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University of Medical Sciences

Street address

azadegan street-dental school

City

zahedan

Province

Sistan-va-Balouchestan

Postal code

98176996930

Approval date

2023-02-26, 1401/12/07

Ethics committee reference number

IR.ZAUMS.REC.1402.006

Health conditions studied

1

Description of health condition studied

The quantity and quality of saliva

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

salivary PH rate

Timepoint

Before use, 1.5 and 10 minutes after use

Method of measurement

ph-meter

Secondary outcomes

1

Description

salivary volume

Timepoint

Before starting the study - after the intervention

Method of measurement

ml/minute

Intervention groups

1

Description

Intervention group: 1: In this group ,the participant receives 1 biodent gum(cinamon) 1 once and chews gum for five minutes.

Category

Other

2

Description

Intervention group2: Intervention group: 1: In this group ,the participant receives 1 Action gum(cinamon) 1 once and chews gum for five minutes.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan dental school

Full name of responsible person

Masoomeh Shirzaiy

Street address

Azadegan street- Zahedan Dental School

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

Azadegan street -Zahedan Dental School

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817699693

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

Masoomeh Shirzaiy

Position

Associated Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Zahedan-Azadegan Street-Dental School

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

Azadegan-Dental School

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

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Azadegan-Dental School

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