

# 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

Masoomah 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

Masoomah 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

Masoomah 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