

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The effects of chewing gum on the formation of plaque on the smooth surface theeth

#### Protocol summary

##### Study aim

Determine the effect of chewing gum on the formation of plaque in smooth surfaces

##### Design

In this study, 18 people with complete oral and dental health who are eligible for entering the study are chosen among people who refer to the dental school.

Participants are randomly divided into intervention and control groups and each participant is assigned a code.

##### Settings and conduct

This study is performed on a randomized clinical trial in the dental school. This study is done in a one-way blind fashion, so that someone who measures the indexes is not aware that which group have used gum and which group is without chewing gum.

##### Participants/Inclusion and exclusion criteria

The participants are from the dental faculty Entry requirements: Full health of the mouth and teeth  
Conditions of non-entry: People with underlying disease and rapidly progressive caries and orthodontic bracket and severe dental arrhythmias

##### Intervention groups

Case group: A group giving them chewing gum. Control group: A group that does not have chewing gum.

##### Main outcome variables

O'Leary index: Measuring dental plaque on smooth surfaces  
Bleeding index: Assessment of bleeding gums around each tooth

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171015036782N4**

Registration date: **2018-04-28, 1397/02/08**

Registration timing: **retrospective**

Last update: **2018-04-28, 1397/02/08**

Update count: **0**

##### Registration date

2018-04-28, 1397/02/08

##### Registrant information

###### Name

farzane vaziri

###### Name of organization / entity

Shahid sadoughi dental university

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3620 4764

###### Email address

f.vaziri@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Sadoughi University of Medical Sciences Yazd

##### Expected recruitment start date

2017-09-23, 1396/07/01

##### Expected recruitment end date

2018-02-20, 1396/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of chewing gum on the formation of plaque on the smooth surface theeth

##### Public title

The effects of chewing gum on the formation of plaque on the smooth surface theeth

##### Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Full health of the mouth and teeth

### Exclusion criteria:

Underlying disease and rapidly progressive caries with orthodontic bracket and severe dental irregularities

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Outcome assessor
- Data analyser

## Sample size

Target sample size: **18**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization using random allocation software, so 18 eligible patients randomly divide into two groups of 9 patients with making special codes.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

The outcome evaluator The person who measures the indexes does not know which group is chewing gum and which group is not chewing gum.

## Placebo

Not used

## Assignment

Crossover

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahid Sadoughi University of Medical Sciences

##### Street address

yazd.Bahonar Square

##### City

yazd

##### Province

Yazd

##### Postal code

8916978477

#### Approval date

2017-06-20, 1396/03/30

#### Ethics committee reference number

ir.ssu.rec.1396.69

## Health conditions studied

### 1

#### Description of health condition studied

gingivitis

#### ICD-10 code

K05.1

#### ICD-10 code description

Chronic gingivitis

## Primary outcomes

### 1

#### Description

bleeding index

#### Timepoint

Once at the end of the period

#### Method of measurement

Evaluation of the bleeding gingiva around each tooth as percentage

### 2

#### Description

o,leary index

#### Timepoint

Once at the end of the period

#### Method of measurement

Measuring dental plaque on flat surfaces as percentages

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In the first group, for the two days of intervention, they receive four BIODENT chewing gum made in Iran, which can be used for 20 minutes after three meals and one after evening snack.

#### Category

Prevention

### 2

#### Description

The control group does not receive any intervention.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dental college

**Full name of responsible person**

Farzaneh al-Sadat Vaziri

**Street address**

End of Imam Street, Imam Reza Square, Imam Reza Blvd.

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yazd

**Province**

Yazd

**Postal code**

8914815667

**Phone**

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**Email**

F.VAZIRI@SSU.AC.IR

Farzaneh al-Sadat Vaziri

**Position**

Periodontology specialist / assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work****Street address**

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**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Dr. Amir Houshang Mehrparvar

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**Province**

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**Email**

ah.mehrparvar@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Sadoughi University of Medical Sciences

**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**

Shahid Sadoughi University of Medical Sciences

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

Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Farzaneh al-Sadat Vaziri

**Position**

Periodontology specialist / assistant professor

**Latest degree**

Subspecialist

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Farzaneh al-Sadat Vaziri

**Position**

Periodontology specialist / assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

Yes - There is 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

**Title and more details about the data/document**

The whole data is shared

**When the data will become available and for how long**

5 months after the publication of the article

**To whom data/document is available**

Researchers working in academic institutions

**Under which criteria data/document could be used**

Email, phone call

**From where data/document is obtainable**

Maryam al-Sadat Kamal al-Dini 09131584672

kamaladdini1373@gmail.com

**What processes are involved for a request to access data/document**

After sending the data, the data will be transmitted

**Comments**