

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Examine the effect of Classic Gum and Sensivital Gum toothbrushes on periodontal indexes in pregnant women

#### Protocol summary

##### Summary

Aim: Examine the effect of Classic Gum and Sensivital Gum toothbrushes on periodontal indexes among pregnant women attending private clinic in districts 2 and 22 in Tehran. Design of study: Interventional, unlimited aging, single blind, without placebo, parallel, prevention, randomized Inclusion criteria: Women in the second trimester of pregnancy, with no systemic diseases such as diabetes and high blood pressure without drugs and without history of high-risk pregnancy, gingival index of at least 1.5 Exclusion criteria: Violation of any of the above condition. Sample size: 52 persons Interventions of study: Classic Gum and Sensivital Gum toothbrushes Time of intervention: Before intervention , 14 days and 28 days after intervention Outcomes of study: Gingival index, plaque index and probing pocket depth Bass method brushing with Complete Crest toothpaste for two minutes in the morning and night and use floss and mouthwash are not used.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013123116019N1**  
Registration date: **2014-08-07, 1393/05/16**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2014-08-07, 1393/05/16

##### Registrant information

##### Name

Elham Mostafa

##### Name of organization / entity

Dental school of Islamic Azad University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2256 4571

##### Email address

k-saebi@dentaliau.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

private

##### Expected recruitment start date

2014-08-11, 1393/05/20

##### Expected recruitment end date

2014-11-16, 1393/08/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Examine the effect of Classic Gum and Sensivital Gum toothbrushes on periodontal indexes in pregnant women

##### Public title

Effects of two toothbrushes in pregnant women

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: Women in the second trimester of pregnancy, with no systemic diseases such as diabetes and high blood pressure without drugs and without history of high-risk pregnancy, gingival index of at least 1.5 Exclusion criteria: Violation of any of the above condition

##### Age

From **15 years** old to **55 years** old

##### Gender

Female

### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: 52

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

Bass method brushing with Complete Crest toothpaste for two minutes in the morning and night and use floss and mouthwash are not used Because of the parallelism, there is no difference between the intervention group and the control. In fact, there is no control group. Patient groups and have each group is given a toothbrush and manual toothbrushes are compared. Referred for researchers. Toothbrushes to give to patients is performed by someone other than the researcher and the researcher does not know which toothbrush is given to each patient.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Dental school of Islamic Azad University

##### Street address

No. 4, 10th Neyestan, Pasdaran St.

##### City

Tehran

##### Postal code

19585/175

#### Approval date

2014-05-26, 1393/03/05

#### Ethics committee reference number

پ/160/د

## Health conditions studied

### 1

#### Description of health condition studied

Gingivitis

#### ICD-10 code

K05

## ICD-10 code description

Gingivitis and periodontal diseases

## Primary outcomes

### 1

#### Description

Gingival index

#### Timepoint

Before intervention, 14 days and 28 days after intervention

#### Method of measurement

Periodontal probe used to score each tooth

### 2

#### Description

Plaque index

#### Timepoint

Before intervention, 14 days and 28 days after intervention

#### Method of measurement

Dental explorer used to score each tooth

### 3

#### Description

Probing pocket depth

#### Timepoint

Before intervention, 14 days and 28 days after intervention

#### Method of measurement

Applications of periodontal probe in millimeters

## Secondary outcomes

### 1

#### Description

Gingivitis

#### Timepoint

Before intervention, 14 days and 28 days after intervention

#### Method of measurement

The use of the dental explorer and periodontal probe

## Intervention groups

### 1

#### Description

Classic Gum tooth Country of manufacturer: Sunstar corporate America Company importer: MGTD company in Iran Application procedure: Bass method for two minutes morning and night

#### Category

Prevention

### 2

#### Description

Sensivital Gum tooth Country of manufacturer: Sunstar corporate America Company importer: MGTD company in Iran Application procedure: Bass method for two minutes morning and night

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Dental school of Islamic Azad University

**Full name of responsible person**

Elham Mostafa

**Street address**

No. 4, 10th Neyestan, Pasdaran St.

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, dental school of Islamic Azad University

**Full name of responsible person**

Arash Azizi

**Street address**

No. 4, 10th Neyestan, Pasdaran St.

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, dental school of Islamic Azad University

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Dental school of Islamic Azad University

**Full name of responsible person**

Khosro Saebi

**Position**

Associate Professor of Islamic Azad University

**Other areas of specialty/work**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Dental school of Islamic Azad University

**Full name of responsible person**

Elham Mostafa

**Position**

Senior dental student

**Other areas of specialty/work**

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**Person responsible for updating data**

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**Name of organization / entity**

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**Full name of responsible person**

Elham Mostafa

**Position**

Senior dental student

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**Web page address**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*