

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

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Email address

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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.

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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.

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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

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

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Full name of responsible person

Elham Mostafa

Position

Senior dental student

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

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

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Full name of responsible person

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Position

Senior dental student

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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