

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The efficacy of brushing and flossing sequence on interdental plaque reduction in young subjects with intact papilla; cross over clinical trial

Protocol summary

Study aim

Determining the effect of brushing and flossing sequence on the reduction of interdental plaque in young subjects with intact papilla

Design

The sampling method is available from dental students of Qazvin Dental School. This study will have two phases. There will be a two-week interval between the two phases to eliminate the effect of the first phase of the study. The sample size was estimated at 37 people.

Settings and conduct

Participants will be given a soft toothbrush, toothpaste and floss. This study will be done in two phases and each phase will last 48 hours. There will be a two-week interval between the two phases. Before the start of each phase for individuals Professional prophylaxis will be performed with rubber cup and prophylaxis paste. They will then be asked to refrain from any activity for 48 hours to control plaque and maintain oral hygiene. After 48 hours, participants will randomly enter the first group (brush). -floss) or the second group (floss-brush). Group 1 (brush-floss): First, participants will be given a disclosing detector tablet. Then the index plate will be taken by Rustogi Modified navy plaque index method. Then the toothbrush with modified bass method for 2 minutes and then floss for 2 minutes will be used. Then the index plate will be registered again. The second group (Floss-brush): All the steps are similar to the first group, except that first floss and then toothbrush will be used.

Participants/Inclusion and exclusion criteria

Participants will be dental students of Qazvin Dental School, whose average age is 20 to 25 years. Individuals must meet the inclusion criteria

Intervention groups

Before each study phase, prophylaxis will be performed for participants with a brush and prophylaxis paste.

Main outcome variables

Reduction of interdental plaque

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210803052063N1**

Registration date: **2021-11-06, 1400/08/15**

Registration timing: **prospective**

Last update: **2021-11-06, 1400/08/15**

Update count: **0**

Registration date

2021-11-06, 1400/08/15

Registrant information

Name

Fahimeh AliAkbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3355 5625

Email address

aliakbaryfahimeh977@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-05, 1400/09/14

Expected recruitment end date

2022-01-04, 1400/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of brushing and flossing sequence on interdental plaque reduction in young subjects with intact papilla; cross over clinical trial

Public title

The efficacy of brushing and flossing sequence on plaque

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Does not exist crown on teeth Having all their permanent teeth(except third molars) Individuals with a normal unstimulated salivary flow rate Individuals free from cavitated carious lesions Intact papilla at interdental area

Exclusion criteria:

Systemic illness or periodontitis Severe crowding Gingival recession Diastema

Age

From **20 years** old to **25 years** old

Gender

Both

Phase

2

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **37**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization. The method of randomization is that a person other than the facilitator of the envelope will give statistics to the participants according to the list of consultants and they will be asked to implement the envelope about the content of the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the performer and statistical analyzer will be blind until after data analysis. First, the list is prepared by a statistical consultant, in which sequence do the numbers 1 to 37 enter first, and in each phase, first brush or floss? Then, a person other than the presenter randomly selects a number from 1 to 37 for each person and categorizes the statistics of the people according to the list. The paper is given to the participants for each person who enters the sequence first. While studying, brushing and flossing leaves the presenter alone to be completely blind

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Qazvin University of Medical Sciences

Street address

Bahonar blvd. Qazvin university of medical science

City

Qazvin

Province

Qazvin

Postal code

15315-34199

Approval date

2021-06-07, 1400/03/17

Ethics committee reference number

IR.QUMS.REC.1400.106

Health conditions studied**1****Description of health condition studied**

Dental plaque

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes**1****Description**

Calculation of dental plaque using modified navy plaque index

Timepoint

The study will be conducted in two phases. On the first day of the first phase of prophylaxis and on the third day of the first phase, the index plate will be recorded. After two weeks, on the first day of the second phase of prophylaxis and on the third day of the second phase, the index plate will be registered.

Method of measurement

Modified navy plaque index

Secondary outcomes

empty

Intervention groups**1****Description**

This is a crossover study that will performed in two phases. At the beginning of each phase, prophylaxis will be performed for the participants for all dental surfaces using golchadent prophylaxis Paste, Golchai co, Alborz,

Iran prophylaxis brush and prophylaxis paste. they will asked to discontinue all forms of oral hygiene for 48 hours. In one phase, they will first brush, then floss. In the other phase they initially will use dental floss then brush.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin University of Medical Sciences

Full name of responsible person

Fahimeh Ali Akbari

Street address

Qazvin University of Medical Sciences, Bahonar Blvd.

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyed Mahdi Mirhashemi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Fahimeh Ali Akbari

Position

dentistry student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All shareable information except people's names

When the data will become available and for how long

Access starts 3 months after the results are published

To whom data/document is available

The fable community is accessible to everyone

Under which criteria data/document could be used

The use of data is free to the public

From where data/document is obtainable

Qazvin Dental School Library

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

Visit the library of the School of Dentistry

Comments