

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison between the effects of chewing apple and tooth brushing on dental plaque in dental students of Hamadan in 1399 : A clinical trial

Protocol summary

Study aim

Evaluation of the effect of chewing apple and toothbrushing on dental plaque removal in dental students

Design

48 dental students (24 females and 24 males) of Hamadan dental school whose ages were between 20 to 25 years with good oral hygiene are randomly selected after obtaining informed consent. Students are given a complete description of the study process such as performing the Bass Technique and the duration of each phase. There is a 2 week interval after each group completed their first phase.

Settings and conduct

The students are divided into two groups randomly without using any other complementary plaque control techniques for 24 hours. The plaque index was determined at 3 points: 1. At baseline (after prophylaxis and sample matching) 2. Immediately after performing the plaque removal technique. 3. 24 hours after completing the removal technique. For 24 hours after completing the removal technique, participants do not perform their routine oral hygiene techniques, drink alcohol or consume food that could promote mechanical plaque removal, although they maintain their usual dietary habits. The O'Leary index is used to record dental plaque and the plaque index is recorded in the dental chart by using disclosing tablets in the morning (between 9 o'clock to 12). Patients are asked to hold TEPE plaque search tablets in their mouths for 30 seconds to mix with their saliva and subsequently spread them to all tooth surfaces with their tongues.

Participants/Inclusion and exclusion criteria

1. Good oral hygiene (plaque index must be below 20%)
2. 24 examinable teeth (excluding third molars and teeth with crown, active caries and cavitated teeth and orthodontic appliances)

Intervention groups

Phase 1: tooth brushing, chewing apple Phase 2: chewing

apple, tooth brushing

Main outcome variables

Dental plaque reduction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191214045728N1**

Registration date: **2020-04-17, 1399/01/29**

Registration timing: **prospective**

Last update: **2020-04-17, 1399/01/29**

Update count: **0**

Registration date

2020-04-17, 1399/01/29

Registrant information

Name

Farzad mojarad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3835 4016

Email address

farzadmojarad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-09, 1399/03/20

Expected recruitment end date

2020-09-10, 1399/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison between the effects of chewing apple and tooth brushing on dental plaque in dental students of Hamadan in 1399 : A clinical trial

Public title
Comparison of the effect of chewing apple and tooth brushing on dental plaque

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Good oral hygien (plaque index below 20%) 24 examinable teeth (excluding third molar and teeth with prosthetic treatment, active caries and cavity and orthodontic appliance)
Exclusion criteria:
Smoking Fixed or removable prosthesis History of antibiotic and antiseptic mouthwash consumption for the past 3 months Systemic problem or consumption of saliva-decreasing medications

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave. Hamadan, Islamic Republic of Iran.

City
Hamadan

Province
Hamadan

Postal code
65417838741

Approval date
2019-12-23, 1398/10/02

Ethics committee reference number
IR.UMSHA.REC.1398.772

Health conditions studied

1

Description of health condition studied

Dental plaque

ICD-10 code

K03.6

ICD-10 code description

بیماریهای بافتهای سخت دندانها

Primary outcomes

1

Description

Decrease in dental plaque

Timepoint

1. Baseline, before scaling and matching samples immediately after tooth brushing/ chewing apple 3. 24 hours after tooth brushing/ chewing apple

Method of measurement

Plaque index (O'Leary index) and disclosing tablet

Secondary outcomes

empty

Intervention groups

1

Description

chewing apple: Apples must be consumed along with their peel and the apples used are golden, with a mean weight of 160 grams. Mastication was performed with both sides of the mouth with no time limit. Consumption of apples in 24 hours is intervention number 1.

Category

Prevention

2

Description

tooth brushing: medium toothbrush (Oral-B 123 classic care medium)and sterile water (10 mL), with no toothpaste. The Bass tooth brushing technique is implied for a total of two minutes (30 seconds per quadrant of the oral cavity). There is a one time frequency for brushing in 24 hours.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Pediatric Dentistry, Hamadan
University of Medical Sciences

Full name of responsible person

Niloufar Entezari

Street address

Pediatric Dentistry Department, Hamadan University
of Medical Sciences, Shahid Fahmideh Ave. Hamadan,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Deputy of research and technology, Hamadan
University of Medical Sciences, Shahid Fahmideh Ave.
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s_bashirian@yahoo.com

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Niloufar Entezari

Position

Resident of pediatric dentistry.

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Pediatric Dentistry Department, Hamadan University
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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

The study data file will be used only in the present study.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The published article of the study is accessible under the relevant rules by citation.

When the data will become available and for how long

From the time the results were published until Hamadan University of Medical Sciences granted access to the data.

To whom data/document is available

Hamadan University of Medical Sciences users

Under which criteria data/document could be used

In order to be used in research similar to the citation requirement in the references.

From where data/document is obtainable

To the website of Hamadan University of Medical Sciences or responsible author.

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

Process specified on the university site.

Comments