

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of Clinical Effect of Hydroalcoholic Extract of Whole Pomegranate Fruit on Dental Plaque Formation in 8-10-Year-Old Children

Protocol summary

Study aim

Evaluation of the Clinical Effect of Pomegranate Mouthwash on Plaque Formation in 8-10 year Old Children.

Design

This Clinical Study is Conducted on 14 Children aged 8-10 years in a Cross-over Design, and based on a Random Table, they receive 38% Pomegranate Mouthwash and 0.12% Chlorhexidine.

Settings and conduct

In the First Meeting, Prophylaxy is performed for all Participants in the Pediatric Department of Tehran Islamic Azad Dental School and After 2 Days of Lack of Hygiene, A PI is Recorded, and the First Mouthwash is consumed for 2 Days and the PI is Recorded, and After a Week of wash out, the order of using the Second Mouthwash Begins. Plaque Evaluation is performed by a Pediatric Dental Specialist who is not Aware of the Study Groups, and the Participants receive Mouthwashes with and without Frames.

Participants/Inclusion and exclusion criteria

Systemic Health, No Antibiotic Intake within the Past 3 Weeks Prior to the Study Onset, Absence of Oral Habits, No Use of Orthodontic Or Prosthetic Appliances, No Zerostomia, No Periodontal Disease, and Absence of Active Caries in the Buccal and Lingual Surfaces of Maxillary Right First Molar, Mandibular Left First Molar, Maxillary Left Lateral Incisor, Mandibular Right Lateral Incisor, Maxillary Right Central Incisor, and Mandibular Left Central Incisor.

Intervention groups

Participants will receive 38% Pomegranate Mouthwash and 0.12% Chlorhexidine Mouthwash in a Crossover Design.

Main outcome variables

The Amount of Dental Plaque

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230110057104N1**

Registration date: **2023-02-17, 1401/11/28**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-17, 1401/11/28**

Update count: **0**

Registration date

2023-02-17, 1401/11/28

Registrant information

Name

Mandana Alamdari mahd

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2247 4299

Email address

m.alamdari@student.iautmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-05, 1401/11/16

Expected recruitment end date

2023-02-25, 1401/12/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Clinical Effect of Hydroalcoholic Extract of Whole Pomegranate Fruit on Dental Plaque Formation in 8-10-Year-Old Children

Public title

Evaluation of Effect of Hydroalcoholic Pomegranate Extract on Plaque Formation

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Systemic Health No Antibiotic Intake within the Past 3 Weeks Prior to the Study Onset Absence of Oral Habits No Use of Orthodontic or Prosthetic Appliances No Xerostomia No Periodontal disease, and Absence of Active Caries in the Buccal and Lingual Surfaces of Maxillary Right First Molar, Mandibular Left First Molar, Maxillary Left Lateral Incisor, Mandibular Right lateral Incisor, Maxillary Right Central Incisor, and Mandibular Left Central Incisor. Age 8-10 years

Exclusion criteria:

Lack of cooperation to use mouthwash Taking another mouthwash now Allergy to mouthwash ingredients Not paying attention to the instructions during the study, including not using gum and not brushing teeth in 48 hours

Age

From **8 years** old to **10 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **14**

Randomization (investigator's opinion)

Randomized

Randomization description

This cross-over study includes two treatments A (framed mouthwash) and B (unframed mouthwash) and people are placed in AB and BA groups in a simple random manner using a table of random numbers with the help of Rand option of Excel software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The two mouthwashes are completely identical in terms of the bottle, color, and by adding flavoring, and the mouthwashes are given to the participant in framed and unframed form with the indication of how to use them. Plaque evaluation and data collection is done by a pediatric specialist who is not aware of the studied groups.

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

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

Ethics Committee of Faculty of Dentistry, Tehran Islamic Azad University of Medical Sciences

Street address

No 11, Yas Ave, Sohanak, Tehran

City

Tehran

Province

Tehran

Postal code

1955819973

Approval date

2023-02-04, 1401/11/15

Ethics committee reference number

IR.IAU.PS.REC.1401.424

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

The effect of Mouthwash on the Formation of Microbial Plaque

ICD-10 code

K02

ICD-10 code description

Dental caries

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

The Amount of Dental Plaque Formation

Timepoint

3,5,14

Method of measurement

Dental Plaque Disclosing Tablets

Secondary outcomes

empty

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

Intervention group:10 mL of the Hydroalcoholic Pomegranate mouthwash rinse twice a day and then spit it out for 2 days.

Category

Prevention

2**Description**

Control group: 10 mL of the chlorhexidine mouthwash rinse twice a day and then spit it out for 2 days.

Category

Prevention

Recruitment centers1**Recruitment center****Name of recruitment center**

Faculty of Dentistry, Islamic Azad University of Tehran

Full name of responsible person

Mandana Alamdari Mahd

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Alireza Khoshdel

Street addressTehran Islamic Azad University of Medical Sciences,
Shariati St, Aine Blvd, Tehran**City**

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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

Islamic Azad University

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**

Islamic Azad University

Full name of responsible person

Sara Tavassoli Hojati

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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

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Fax**Email**

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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

Participants do not wish to share their information.

Study Protocol

Yes - There is 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

Information related to the outcome of the study and the study protocol will be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

Researchers who have a research plan in this field.

Under which criteria data/document could be used

If the information is preserved.

From where data/document is obtainable

alamdarimandana@yahoo.com

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

Send a Message to the said Email, if Similar Research Work is done in this Field, Sufficient Information Regarding the Results and Study Protocol will be Emailed.

Comments