

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Preparation and characterization of honey based toothpaste and comparing its anti-plaque effect with Iran-made and imported toothpaste

Protocol summary

Study aim

Comparing the effectiveness of honey-based toothpaste in reducing dental plaque with common Iranian and foreign toothpastes

Design

Parallel-group trial with the control group, randomized with 117 participants, the block method will be used to assign people to treatment groups randomly.

Settings and conduct

The place of study is Alborz Dental Faculty. After fully explaining the materials used to the patients and informing them, informed consent will be obtained from the patients. Before starting the trial process, the candidates are examined for periodontal problems and dental plaque. Candidates are taught how to brush their teeth and necessary considerations to standardize the study process such as brushing time, etc. Also, all the candidates will be given the same toothbrush.

Participants/Inclusion and exclusion criteria

Participants must have at least 20 teeth and their oral and dental health has been confirmed.

Intervention groups

After recording the plaque index of each person, the 39 people of the first group are given formulated toothpaste and we ask them to use it during the week and come back at the end of the week to re-record the plaque index. In order to register the plaque index, each person is given a disclosing agent and the necessary explanations are given to the candidate regarding the side effects of this substance. Sampling is accessible and easy. The person who evaluates dental plaque is unaware of the groups and the type of intervention they received. This action is repeated for three weeks by the volunteer. So that all people will be checked for dental plaque 3 times and at weekly intervals. All steps are the same for the second and third groups who used Iranian and imported toothpaste, respectively.

Main outcome variables

Changing dental plaque

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230121057172N1**

Registration date: **2023-02-04, 1401/11/15**

Registration timing: **prospective**

Last update: **2023-02-04, 1401/11/15**

Update count: **0**

Registration date

2023-02-04, 1401/11/15

Registrant information

Name

Mohaddeseh Sarzaeem

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3256 7175

Email address

m.sarzaeem98@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preparation and characterization of honey based toothpaste and comparing its anti-plaque effect with Iran-made and imported toothpaste

Public title

Comparing the effectiveness of honey toothpaste with two common types of toothpaste

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Participants must have at least 20 teeth Oral and dental health of the participants must be confirmed.

Exclusion criteria:

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **117**

Randomization (investigator's opinion)

Randomized

Randomization description

To investigate the effect of this toothpaste on dental plaque removal, a randomized clinical trial will be used to determine the plaque score. For this purpose, 117 volunteers are randomly selected among the students and divided into three groups of 39 people. The block method will be used to randomly assign people to treatment groups. After fully explaining the materials used and informing the patients, informed consent will be obtained from the patients.

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 Alborz University of Medical Sciences

Street address

Valiasr Blvd.

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2022-12-17, 1401/09/26

Ethics committee reference number

IR.ABZUMS.REC.1401.273

Health conditions studied

1

Description of health condition studied

plaque index

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

plaque index

Timepoint

0, 7, 14 and 21 days after beginning

Method of measurement

Evaluation of plaque index by disclosing agents

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: honey based toothpaste given

Category

Other

2

Description

Intervention group2: Iranian toothpaste given

Category

Other

3

Description

Intervention group3: Foreign Toothpaste given

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry of Alborz University of Medical

Sciences

Full name of responsible person

Mohaddeseh Sarzaeem

Street address

Katoiee zade St., Golshahr

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Mohaddeseh Sarzaeem

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Razieh Lotfi

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Research@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Person responsible for scientific inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mohaddeseh Sarzaeem

Position

Student

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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

Undecided - It is not yet known if there will be 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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

Not applicable