Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effect of coconut oil and pomegranate peel extract mouthwash on plaque-induced gingivitis with chlorhexidine mouthwash

Protocol summary

Study aim
Clinical study of the effect of mouthwash containing coconut oil and pomegranate peel extract on plaque-induced gingivitis.

Design
The clinical trial has two groups of 20 people, randomized in a parallel, double-blind manner, and is in Phase 3 of the clinical trial. Randomization is done using a random number table. Random number tables are generated by computers that randomly arrange numbers.

Settings and conduct
Patients will be divided into 2 groups of 20 people based on the available indicators. Patients in the 2 groups will be matched in terms of gender. The double-blind cross-over method will be implemented; the patient and the relevant oral disease specialist will not know the contents of the bottle. The allocation of individuals to each group will remain hidden from the patient and the examining dentist until the end of the study. On the first day, scaling and brushing will be performed for all patients, and then the study group will use an oil-based mouthwash (10 ml) twice a day for 2 minutes for 14 days as a mouthwash, and the control group will use CHX twice a day for 14 days. On day 14, plaque index and BOP and gingival index are measured and recorded again.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Presence of plaque and calculus on dental surfaces, presence of clinical signs of gingivitis, age range 18 to 65 years. Exclusion criteria: People with any systemic disease, pregnant and breastfeeding mothers, people who used mouthwash, received chemotherapy or antibiotic treatment, patients with poor motivation and/or poor cooperation, patients treated with calcium antagonists, cyclosporine and phenytoin, and patients who are allergic to coconut.

Intervention groups
The intervention group uses the desired mouthwash, and the control group uses chlorhexidine mouthwash.

Main outcome variables
plaque index, gingival index, BOP

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250811066829N1**
Registration date: **2025-10-06, 1404/07/14**
Registration timing: **prospective**

Last update: **2025-10-06, 1404/07/14**
Update count: **0**

Registration date
2025-10-06, 1404/07/14

Registrant information

Name
Negin Seyedmardani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-12, 1404/07/20

Expected recruitment end date
2025-11-16, 1404/08/25

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of coconut oil and pomegranate peel extract mouthwash on plaque-induced gingivitis with chlorhexidine mouthwash

Public title

Comparison of the effect of coconut oil and pomegranate peel extract mouthwash on plaque-induced gingivitis with chlorhexidine mouthwash

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The age range of people is between 18 and 65 years old. Have clinical signs of gingivitis. Have plaque and calculus on tooth surfaces

Exclusion criteria:

People with any systemic disease. Pregnant and breastfeeding mothers. People who used mouthwash. People who have had chemotherapy or are being treated with antibiotics. Patients with poor motivation and/or poor cooperation. Patients treated with calcium antagonists, cyclosporine, and phenytoin. Patients who are allergic to coconut.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Before using the desired mouthwash, the periodontal status of the volunteers is checked and these volunteers are randomly assigned to one of the intervention and control groups using a random number table so that the distribution of oral health and disease status is the same between the two groups. The method of randomization is done using a random number table. Random number tables are prepared by computers that randomly arrange the numbers. These tables have random numbers in both rows and columns, which usually add up to 99 rows and columns, and the numbers in the rows and columns are placed next to each other and separated in five-digit blocks to facilitate their use.

Blinding (investigator's opinion)

Double blinded

Blinding description

Because the study is double-blind, except for the consultant supervisor as the third person in the study, none of the volunteers or students carrying out the project are aware of the placement of the study subject in the control or intervention group. In order to maintain confidentiality of the information for the individuals who were determined. The mouthwash container will be the same, Also, opaque containers will be used, so the contents of the containers will not be visible and no one other than the relevant professor will know how the mouthwash is distributed among the patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences (Dentistry faculty)

Street address

Azadi Street, Golgasht Street, Attarnishabori Street, Faculty of Medicine, Research Development and Coordination Center (RDCC)

City

Tabriz

Province

East Azarbaijan

Postal code

5166/15731

Approval date

2025-07-29, 1404/05/07

Ethics committee reference number

IR.TBZMED.DENTISTRY.REC.1404.029

Health conditions studied

1

Description of health condition studied

Patients with gingivitis

ICD-10 code

K05.10

ICD-10 code description

Chronic gingivitis, plaque induced

Primary outcomes

1

Description

Plaque Index: This refers to the presence or absence of plaque on the 6 surfaces of the teeth, which is measured on all teeth present in the patient's mouth.

Timepoint

14 days after using mouthwash

Method of measurement

The plaque index (DPI) is calculated using the O'Leary index (this index is useful for assessing the plaque control performance of patients and is relatively easy, reproducible and inexpensive to determine). For this purpose, the patient's mouth is first rinsed with plain water and the surfaces of his teeth are stained using a dye that is revealed to detect dental plaque. In the next step, the discoloration of the different surfaces of each tooth is examined. For this purpose, each stained surface will be examined for the accumulation of plaque-revealing tablets at the tooth-gingival junction and the stained areas will be recorded with a red mark on the form. Finally, the number of discolored surfaces is divided by the number of teeth multiplied by six (or the total number of stained surfaces) and expressed as a percentage.

2

Description

Gingival index :The gingival index (GI) is defined as a tool used to assess the severity of gingival inflammation based on the thickness and accumulation of plaque and debris, which helps evaluate patient adherence to oral hygiene practices.

Timepoint

14 days after using mouthwash

Method of measurement

The gingival index is recorded by the examiner using a Williams probe. The Löe & Silness method is used to assess the gingival index. The gingiva of each tooth is divided into four sections: mesiobuccal, distobuccal, midbuccal, and midlingual. Each section is scored from 0 to 3. If the gingiva appears normal and is not bleeding, a score of 0 is assigned; if there is little inflammation and no bleeding on probing, a score of 1; if there is moderate inflammation and bleeding on probing, a score of 2; and if there is severe inflammation and spontaneous bleeding, a score of 3. To obtain the gingival index of each tooth, the average gingival index of the surfaces of that tooth is calculated; and to obtain the gingival index of the entire mouth, the average gingival index of all teeth is calculated.

3

Description

BOP index: Bleeding on probing (BOP) is the primary parameter to set the threshold for gingivitis.

Timepoint

14 days after using mouthwash

Method of measurement

The Ainamo & Bay index will be used to measure the amount of bleeding from the gums (BOP). The probe is gently inserted into the gingival sulcus and after 10 seconds the presence or absence of bleeding is checked.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group :The study group of 20 people will use 10ml of mouthwash containing coconut oil twice a day after waking up and before going to bed for 2 minutes.

Category

Treatment - Drugs

2

Description

Control group: The control group of 20 people will use CHX (chlorhexidine mouthwash) twice a day according to the manufacturer's instructions.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz University of Medical Sciences

Full name of responsible person
Maryam Kouhsoltani

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Ground floor, Building of the Faculty of Dentistry,Tabriz University of Medical Sciences, Tabriz University, Golgasht Avenue, Tabriz, Iran

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Farshad Javadzadeh

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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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

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