

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of cardamom herbal mouthwash with 0.2% chlorhexidine on plaque index and gingival index

Protocol summary

Study aim

Determining the effect of herbal cardamom mouthwash with 0.2% chlorhexidine on plaque and gingivitis indices

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, performed on 23 patients

Settings and conduct

The study is performed in the School of Dentistry of Isfahan Azad University and patients are divided into three groups, including chlorhexidine mouthwash group, cardamom mouthwash group and placebo group, in which both patients and researchers are unaware of the contents of the bottle.

Participants/Inclusion and exclusion criteria

23 patients with gingivitis will be selected. The patients should be free of any systemic disease and have not taken any medication that causes hyperplasia and bleeding gums in the last 6 months. Patients with periodontitis and recipients of periodontal treatments, smokers and pregnant women, and any other factor that affects the development and course of gum disease are excluded from the study. Patients with symptoms of gingivitis, including gingival discoloration, bleeding when probing without loss of adhesion, and alveolar bone resorption in the probe are selected.

Intervention groups

Chlorhexidine mouthwash group
Cardamom mouthwash group
Placebo Group

Main outcome variables

Independent variable: mouthwash
Dependent variable: plaque index, gingivitis index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220525054989N1**

Registration date: **2022-07-31, 1401/05/09**

Registration timing: **retrospective**

Last update: **2022-07-31, 1401/05/09**

Update count: **0**

Registration date

2022-07-31, 1401/05/09

Registrant information

Name

Zahra Aghajani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-29, 1401/04/08

Expected recruitment end date

2022-07-13, 1401/04/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of cardamom herbal mouthwash with 0.2% chlorhexidine on plaque index and gingival index

Public title

Comparison of the effect of cardamom herbal mouthwash with 0.2% chlorhexidine on plaque index and

gingival index

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with gingivitis Patients with symptoms of gingivitis, including gingival discoloration, bleeding when probing without loss of adhesion, and alveolar bone resorption in the probe are selected.
Exclusion criteria:
The patients studied should be free of any systemic disease Do not take any medication that causes hyperplasia and bleeding gums in the last 6 months Patients with periodontitis and recipients of periodontal treatments, smokers and pregnant women, and any other factor that affects the development and course of gum disease are excluded from the study.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: 23

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The person is asked to pour both mouthwash and placebo into the bottles in a uniform and opaque shape and then bring it to the researcher so that both the person being studied and the researcher do not know what type of substance is inside the bottle. Participate in the study)

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics Committee of Islamic Azad University-Isfahan Branch (Khorasgan)

Street address
Kerman, 33 South Jomhuri Blvd., 3 Star Complex, Unit 8

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kerman

Province
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Postal code
7617998596

Approval date
2022-05-30, 1401/03/09

Ethics committee reference number
IR.IAU.KHUISF.REC.1401.102

Health conditions studied

1

Description of health condition studied

Gingivitis

ICD-10 code

K05.1

ICD-10 code description

Chronic gingivitis

Primary outcomes

1

Description

"The percentage of plaque before and after using mouthwash"

Timepoint

At the beginning of the study and 14 days later

Method of measurement

Disclosure tablets

2

Description

Gingivitis before and after using mouthwash

Timepoint

At the beginning of the study and 14 days later

Method of measurement

prob

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 0.5% cardamom mouthwash group. The treatment method is that cardamom mouthwash is swirled in the mouth twice a day for two weeks and every day for 30 seconds. Plaque and gingivitis index are measured by disclosing tablet and probe before and after

using the mouthwash. Mouthwash concentration is 0.5%. The mouthwash is made by Dr. Darusaz.

Category

Treatment - Drugs

2**Description**

Intervention group: 0.2% chlorhexidine mouthwash group. The treatment method is that chlorhexidine mouthwash is swirled in the mouth twice a day for two weeks and every day for 30 seconds. Plaque and gingivitis index by disclosing tablet and probe before and after using the mouthwash. The concentration of the mouthwash is 0.2% and it is prepared from a pharmacy and is of the Behsa brand.

Category

Treatment - Drugs

3**Description**

Control group: Placebo (water) group. The treatment method is that the water is swirled in the mouth twice a day for two weeks and every day for 30 seconds. The index of plaque and gingivitis is measured by disclosing tablets and probes before and after consuming water. In addition, water bottles are similar to mouthwash bottles.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Iran-Isfahan-Islamic Azad University (Khorasgan) - Dental School

Full name of responsible person

Zahra Aghajani

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Islamic Azad University

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

2**Sponsor****Name of organization / entity**

Islamic Azad University

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

Islamic Azad University

Proportion provided by this source

50

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

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Person responsible for general inquiries

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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