

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of curcumin mouthwash on the indicators of gingivitis and dental plaque in patients referred to the School of Dentistry

Protocol summary

Type of mouthwash used and its effect on dental plaque and gingivitis inflammation

Study aim

Determining the effect of turmeric mouthwash on gingivitis and dental plaque in comparison with chlorhexidine mouthwash and control group in patients referred to the periodontics department of Islamic Azad School of Dentistry in Tehran in 2021

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 51 patients.

Settings and conduct

All steps are performed by 11th and 12th semester students and Tehran Azad School of Dentistry. Blinding is done by coating on clinical caregivers. After entering the study, each candidate randomly and secretly selected the envelope in a package that contains the mouthwash to be tested with a specific code, each code has already been given to a mouthwash. The process of checking the desired indicators and then scaling is done by a trained person who does not know the type of mouthwash used by the patient. After using the mouthwash, it is referred again in the specified period and the desired indicators are measured.

Participants/Inclusion and exclusion criteria

Admission requirements include: Participants with gingivitis and Bleeding on probing(BOP) > 10%, with dental plaque and between 20 to 40 years of age. Non-entry conditions include: pregnant women, people who have had periodontal treatment in the last 6 months, patients treated with systemic antibiotics, smokers with a history of allergies to turmeric.

Intervention groups

Curcumin mouthwash: After scaling, 10ml of turmeric mouthwash is used 10 minutes after brushing and for 30 seconds. For 14 days and 2 times a day. Chlorhexidine mouthwash: After scaling, 10ml of chlorhexidine mouthwash is used 10 minutes after brushing and for 30 seconds. For 14 days and 2 times a day. Control group: only scaling is done and no mouthwash is used.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180714040460N8**

Registration date: **2021-04-10, 1400/01/21**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-10, 1400/01/21**

Update count: **0**

Registration date

2021-04-10, 1400/01/21

Registrant information

Name

Nima Nadafpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 4571

Email address

n_nadaf@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-10, 1400/01/21

Expected recruitment end date

2021-06-04, 1400/03/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of curcumin mouthwash on the indicators of gingivitis and dental plaque in patients referred to the School of Dentistry

Public title

The effect of curcumin mouthwash on the indicators of gingivitis and dental plaque

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

20>Age>40 Dental plaque Bleeding on probing>10% Gingivitis

Exclusion criteria:

Pregnant women People who have had periodontal treatment in the last 6 months History of curcumin sensitivity Tobacco consumers Patients treated with systemic antibiotics

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **51**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients with generalized gingivitis are selected and included in the study. Patients are randomized in a block, so that packages consisting of 9 papers consisting of 3 papers from each group (3 to chlorhexidine, 3 to curcumin and 3 to control) are placed in front of the patient and the patient selects one of them randomly and enters that group, and after the completion of these 9 patients, the next patients (next 9 people) enter the study so that the process of getting sick can proceed simultaneously in all 3 groups. Next, the process of scaling and reviewing the indicators is done by a trained person who does not know what group the patient is in, so as not to be biased.

Blinding (investigator's opinion)

Double blinded

Blinding description

Clinical caregivers and outcome assessors have no idea which groups the participants will be studied in.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tehran Azad University of Medical Sciences

Street address

Neyestan 9 Ave, Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2021-01-08, 1399/10/19

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.159

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

Gingival inflammation and dental plaque

ICD-10 code

K05

ICD-10 code description

Gingivitis and periodontal diseases

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

Dental plaque: Determining the amount of dental plaque is evaluated based on the TURESKY index and is measured after using the disclosure pill and is expressed between 0-5 according to the presence or absence of plaque. Gingivitis: Based on the bleeding areas and based on the Modified Sulcular bleeding index is measured with a periodontal probe and is expressed between 0-3 depending on the presence or absence of bleeding.

Timepoint

Day 0 and day 14

Method of measurement

Dental plaque: Determining the amount of dental plaque is evaluated based on the TURESKY index and is measured after using the disclosure pill and is expressed between 0-5 according to the presence or absence of plaque. Gingivitis: Based on the bleeding areas and based on the Modified Sulcular bleeding index is measured with a periodontal probe and is expressed between 0-3 depending on the presence or absence of bleeding.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients who do not use any mouthwash and the desired indicators (plaque and gingivitis) are measured on the first day and then scaling and after 14 days the indicators are checked again.

Category

Treatment - Other

2

Description

First intervention group: Patients who are initially scaled and after measuring the indicators for 14 days use Najo chlorhexidine mouthwash for 0.2% and the indicators are evaluated 14 more times a day. People who are going to use mouthwash are told to use 10 ml of mouthwash twice a day for 30 minutes after brushing for 30 seconds and do not eat anything for 30 minutes after using the mouthwash.

Category

Treatment - Other

3

Description

Second Intervention group : Patients who are initially scaled and after measuring the indicators for 14 days use curcumin mouthwash 0.2% of Sina Curcumin company and the indicators are evaluated 14 times a day. People who are going to use mouthwash are told to use 10 ml of mouthwash twice a day for 30 minutes after brushing for 30 seconds and do not eat anything for 30 minutes after using the mouthwash.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry, Tehran Azad University of Medical Sciences

Full name of responsible person

Dr. Nima Naddafpour

Street address

Neyestan 9 Ave, Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4570

Email

nima.na04@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Arash Azizi

Street address

Neyestan 9 Ave, Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4570

Email

nima.na04@gmail.com

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

Seyed Navid Mirazimi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

No 1, Fifth Narenjestan Ave, Pasdaran Ave

City

Tehran

Province

Tehran
Postal code
1957917711
Phone
+98 21 2282 6301
Email
navidmirazimi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Nima Naddafpour
Position
Periodontist
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Neyestan 9 Ave, Pasdaran Ave
City
Tehran
Province
Tehran
Postal code
1946853314
Phone
+98 21 2256 4570
Email
nima.na04@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University
Full name of responsible person
Seyed Navid Mirazimi
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
No 1, Fifth Narenjestan Ave, Pasdaran Ave
City
Tehran
Province
Tehran
Postal code
1957917711
Phone
+98 21 2282 6301
Email
navidmirazimi@gmail.com

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

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available