

# 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

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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

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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

Seyed Navid Mirazimi

##### Position

Student

##### Latest degree

A Level or less

##### Other areas of specialty/work

Dentistry

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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

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