

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparing the effect of mouthwash containing curcumin and oral nanocurcumin on gingivitis in patients with chronic gingivitis who referred to Dental School of Shahid Sadoughi

Protocol summary

Study aim

Determining the Comparing the effect of mouthwash containing curcumin and oral nanocurcumin on gingivitis in patients with chronic gingivitis who referred to Dental School of Shahid Sadoughi

Design

Clinical trial, with parallel, randomized, phase 2 on 30 patients, for randomization, a table of random numbers is used.

Settings and conduct

30 patients with chronic gingivitis referred to Yazd Dental School, randomly divided into three groups of 10 people: Chlorhexidine mouthwash, curcumin mouthwash and oral nanocurcumin capsule. In the first session we calculate the indicators by examining each patient, then all patients will be given the same health education and , scaling is done for all of them by ultrasonic means. After two weeks, we will be recording the indicators again.

Participants/Inclusion and exclusion criteria

not having systemic disease, no simultaneous use of anticoagulants and antiplatelets, age group 25 to 65 years old, insensitivity to turmeric and its compounds, No need for antibiotic prophylaxis, no smoking, no use of anti-inflammatory substances for six weeks before and at the time of examination, no attachment loss and no periodontal treatment in the last six months, no pregnancy or breastfeeding.

Intervention groups

1. Mouthwash containing curcumin made in Yazd Faculty of Pharmacy, In the house, 3 times a day and every 20 drops of mouth rinse 0.06% of curcumin in 10 ml water and rinse for 30 seconds for two weeks. 2. Curcumin nano micelle capsule 80 mg (Sina Curcumin, prepared by ExirNanoSina, Tehran, Iran), Once a day after breakfast they will receive. 3. Chlorhexidine mouthwash, at home, use it twice a day for 1 minute according to the recipe and do not drink and eat for 30 minutes after mouth

washing

Main outcome variables

Gingival Index
Plaque Index (silness-loe)
Papillary Bleeding Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220420054592N2**
Registration date: **2024-02-18, 1402/11/29**
Registration timing: **prospective**

Last update: **2024-02-18, 1402/11/29**

Update count: **0**

Registration date

2024-02-18, 1402/11/29

Registrant information

Name

Arezou Khabazian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3625 5881

Email address

a.khabazian@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-26, 1402/12/07

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of mouthwash containing curcumin and oral nanocurcumin on gingivitis in patients with chronic gingivitis who referred to Dental School of Shahid Sadoughi

Public title
Comparing the effect of mouthwash containing curcumin and oral nanocurcumin on gingivitis in patients with chronic gingivitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with chronic gingivitis referred to the periodontics department of dental school No systemic disease (no history of gallstones or gallstone obstruction, no active gastrointestinal diseases, liver disease or immunosuppressive system) Age group 25 to 65 years old By matching age and gender in each group Insensitivity to turmeric and its compounds based on patient's self-declaration Needless to antibiotic prophylaxis Non-smoking Not using anti-inflammatory drugs for six weeks prior to and at the time of the check-up Lack of attachment loss Lack of periodontal treatment in the past six months Lack of pregnancy or breastfeeding No simultaneous anticoagulant and antiplatelet use
Exclusion criteria:
Lack of patient cooperation Having symptoms of curcumin allergy

Age
From **25 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization using Random allocation software

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 Shahid Sadoughi University of Medical Sciences

Street address

Dental School, Imam Reza Blvd., End of Imam Reza St., Yazd, Iran

City

Yazd

Province

Yazd

Postal code

8914815667

Approval date

2023-12-24, 1402/10/03

Ethics committee reference number

IR.SSU.DENTISTRY.REC.1402.064

Health conditions studied

1

Description of health condition studied

Gingivitis

ICD-10 code

K05

ICD-10 code description

Gingivitis and periodontal diseases

Primary outcomes

1

Description

Gingival Index

Timepoint

In the first session and two weeks after the start of using oral rinses or nanocurcumin capsules depending on the patient group

Method of measurement

A probe and principles of the gingival index system identified by Leo

2

Description

Plaque Index

Timepoint

In the first session and two weeks after the start of using oral rinses or nanocurcumin capsules depending on the patient group

Method of measurement

Plaque Index (silness-loe)

3

Description

Papillary Bleeding Index

Timepoint

In the first session and two weeks after the start of using oral rinses or nanocurcumin capsules depending on the patient group

Method of measurement

A probe and record bleeding points around each tooth

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The curcumin mouthwash group, For two weeks, 20 drops of 0.06% curcumin mouthwash in 10 ml water and rinse for 30 seconds 3 times a day.

Category

Treatment - Drugs

2

Description

Intervention group: Oral Nano-Curcumin, 80 mg Curcumin Nanomicelle Capsule (Sina Curcumin, prepared by ExirNanoSina, Tehran, Iran), Once a day after breakfast.

Category

Treatment - Drugs

3

Description

Intervention group: Chlorhexidine mouthwash, at home, use it twice a day for 1 minute according to the recipe and do not drink and eat for 30 minutes after mouth washing.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Dental School

Full name of responsible person

Arezoo Khabazian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amir Hooshang Mehrparvar

Street address

Shahid Sadoughi University of Medical Sciences, Bahonar Sq., Yazd, Iran

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8916978477

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ah.mehrparvar@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd University of Medical Sciences

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

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Arezoo Khabazian

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Arezoo Khabazian

Position

Professor

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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 data.

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