

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of nanocurcumin and chlorhexidine mouthwash effect on the prostaglandin E2 biomarker concentration in gingival crevicular fluid of fixed orthodontic patients

Protocol summary

Registration timing: **prospective**

Study aim

Comparison of nanocurcumin and chlorhexidine mouthwash effect on the level of gingival crevicular fluid prostaglandin E2 of fixed orthodontic patients

Last update: **2023-06-10, 1402/03/20**

Update count: **0**

Registration date

2023-06-10, 1402/03/20

Design

A single blinded blocked randomized clinical trial on patients undergoing fixed orthodontic treatment in four groups (the group using mouthwash containing curcumin nanoparticles, the group using chlorhexidine mouthwash, the group using both nanocurcumin and chlorhexidine mouthwash at the same time, and the control group)

Registrant information

Name

Aliakbar Naghavihosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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Settings and conduct

Orthodontics Department, Dental School, Golestan University of Medical Sciences

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: Agreement to participation in the study, 15 to 35 years old, Passed at least 2 mounts after fixed orthodontics treatment, Negative for hypersensitivity to Curcumin and/or chlorhexidine

Exclusion criteria: The presence of any ulcer or intraoral infection, Severe gingival inflammation or periodontal pocket, Systemic disease, Pregnant and lactating mothers, Antibiotics usage in a month before the study, Fluoride therapy in the last 6 months, Tobacco usage, Corticosteroids and NSAIDs usage

Expected recruitment start date

2023-06-20, 1402/03/30

Expected recruitment end date

2023-10-07, 1402/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

nanocurcumin and chlorhexidine mouthwash application

Main outcome variables

prostaglandin E2 level in gingival crevicular fluid

Scientific title

Evaluation of nanocurcumin and chlorhexidine mouthwash effect on the prostaglandin E2 biomarker concentration in gingival crevicular fluid of fixed orthodontic patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220223054108N2**

Registration date: **2023-06-10, 1402/03/20**

Public title

Effect of nanocurcumin and chlorhexidine mouthwash on level of prostaglandin E2

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Agreement to participation in the study 15 to 35 years old Passed at least 2 mounts after fixed orthodontics treatment Negative for hypersensitivity to Curcumin and/or chlorhexidine

Exclusion criteria:

The presence of any ulcer or intraoral infection Severe gingival inflammation or periodontal pocket Systemic disease Pregnant and lactating mothers Antibiotics usage in a month before the study Fluoride therapy in the last 6 months Tobacco usage Corticosteroids and NSAIDs usage

Age

From **15 years** old to **35 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible subjects will be assigned to the nanocurcumin and chlorhexidine mouthwash groups, the nanocurcumin only and chlorhexidine only, and the control group using the random block method. We first create a random sequence of 11 eight-block random blocks. Random numbers were generated in R software and In each block, each letter A, B, C, D is repeated twice. ABCDACDB, CADBACBD, DACBBCAD, ABBCDACD, CADBACDB,... In the desired sequence, there will be 22 letters from each letter A, B, C, D. According to the above block, 88 envelopes will be prepared, and in each envelope, the letters A, B, C, D will be placed and will be numbered from 1 to 88. The person delivering the envelopes to the patients does not know what is inside. This intervention is a two-sided blind type where the researcher knows the type of mouthwash, but the patients do not know about it. A random sequence is produced by a statistics and methodology consultant who does not have access to patients. Patients who received the letter A in the nanocurcumin mouthwash group, patients who received the letter B in the chlorhexidine group, and patients who received the letter C in the nanocurcumin and chlorhexidine group patients who received the letter D in the control group will be placed.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, only the researcher knows the type of mouthwash prescribed for each patient. Nurses and

patients do not have any information about the type of mouthwash to use and only receive instructions on how to use it. The random sequence generation is done by the statistics and methodology consultant, but he does not have access to the patients and is in the category of blinded subjects.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Golestan University of Medical Sciences

Street address

5th Shahryar

City

Gorgan

Province

Golestan

Postal code

4913983635

Approval date

2023-03-05, 1401/12/14

Ethics committee reference number

IR.GOUMS.REC.1402.001

Health conditions studied

1

Description of health condition studied

teeth shifting

ICD-10 code

Z51.8

ICD-10 code description

Encounter for other specified aftercare

Primary outcomes

1

Description

Prostaglandin E2 before and two weeks later in all studied groups

Timepoint

Measurement of prostaglandin E2 at the study's baseline (before starting treatment) and two weeks after consuming the prescribed mouthwashes for each group

Method of measurement

Enzyme-linked Immunosorbent Assay (ELISA test)

Secondary outcomes

1

Description

Patients' perception of taste in the group of patients using prescribed mouthwashes

Timepoint

The seventh day after using the prescribed mouthwashes

Method of measurement

Individually asking each of the participants about the taste of the prescribed mouthwash based on a questionnaire to check the quality of mouthwash.

Intervention groups

1

Description

Intervention group: In this group, patients are asked to mix 20 drops of nanocurcumin mouthwash with 10 cc of water and use for 30 seconds as a mouthwash twice a day for two weeks after brushing. Dr. Khori Danesh Bonyan Pharmaceutical Company makes Nanocurcumin mouthwash with a concentration of 2% with confirmation code No. 184620 of Golestan University of Medical Sciences. This mouthwash is prepared with the chemical composition C₂₁H₂₀O₆ with over 70% purity degree and a molecular weight of 368 from Sigma & Aldrich Co.

Category

Prevention

2

Description

Intervention group: In this group, patients are asked to mix 20 drops of 0.2% chlorhexidine mouthwash with 10 cc of water and use for 30 seconds according to the written instruction on the mouthwash twice a day for two weeks after brushing.

Category

Prevention

3

Description

Intervention group: In this group, patients are asked to mix 20 drops of nanocurcumin plus chlorhexidine combined mouthwash with 10 cc of water and use for 30 seconds as a mouthwash twice a day for two weeks after brushing.

Category

Prevention

4

Description

Control group: In this group, patients are asked to use 10 cc of 0.9% normal saline as a mouthwash for 30 seconds as a mouthwash twice a day for two weeks after brushing.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthodontics Department- Dental School- Golestan University of Medical Sciences

Full name of responsible person

Aliakbar Naghavialhosseini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Narges Beigam Mirbehbahani

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Grant name

Grant code / Reference number

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

No

Title of funding source

Gorgan 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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Aliakbar Naghavihosseini

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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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

Not applicable

Data Dictionary

Not applicable