

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of nanocurcumin and chlorhexidine mouthwash on levels of gingival crevicular fluid interleukin 1 and 6 in patients undergoing fixed orthodontics treatment

Protocol summary

Study aim

Comparison of nanocurcumin and chlorhexidine mouthwash on levels of gingival crevicular fluid interleukin 1 and 6 in patients undergoing fixed orthodontics treatment

Design

Single blind clinical trial on patients undergoing randomized block orthodontic treatment in four groups (using a mouthwash containing curcumin nanoparticles, using a chlorhexidine mouthwash and a group using two nanocurcumin and chlorhexidine mouthwashes and the control group)

Settings and conduct

Orthodontics Department, Dental School, Golestan University of Medical Sciences

Participants/Inclusion and exclusion criteria

The subjects' inclusion was based on the following criteria: agreement to participation in the current study, 15 to 35 years old, exhibit good periodontal health, systemically healthy, passed at least 2 months after fixed orthodontics treatment, negative for hypersensitivity to curcumin and/or chlorhexidine. Participants who used tobacco, who had used antibiotics, aspirin or non-steroidal anti-inflammatory drugs (NSAIDs) during the past one month, and pregnant and lactating mothers were excluded from this study.

Intervention groups

nanocurcumin and chlorhexidine mouthwash application

Main outcome variables

interleukin 1 and 6 levels in gingival crevicular fluid

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220223054108N1**

Registration date: **2022-04-03, 1401/01/14**

Registration timing: **prospective**

Last update: **2022-04-03, 1401/01/14**

Update count: **0**

Registration date

2022-04-03, 1401/01/14

Registrant information

Name

Aliakbar NaghaviAlhosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3262 7823

Email address

a.a.nagavi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-20, 1401/01/31

Expected recruitment end date

2023-03-05, 1401/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of nanocurcumin and chlorhexidine mouthwash on levels of gingival crevicular fluid interleukin 1 and 6 in patients undergoing fixed orthodontics treatment

Public title

Effects of nanocurcumin and chlorhexidine mouthwash on levels of interleukin 1 and 6

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Agreement to participation in the current study 15 to 35 years old Good periodontal health Systemically healthy Passed at least 2 mounts after fixed orthodontics treatment Negative for hypersensitivity to Curcumin and/or chlorhexidine.

Exclusion criteria:

Tobacco usage Antibiotics, Aspirin or non-steroidal anti-inflammatory drugs (NSAIDs) usage during the past one month Pregnant and lactating mothers

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- 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. 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. A random sequence is produced by a statistics and methodology consultant who does not have access to patients, and only he knows what is in each number. Patients who received the letter A in the nanocurcumin and chlorhexidine mouthwash group, patients who received the letter B in the nanocurcumin group, and patients who received the letter C in the chlorhexidine group patients who received the letter D in the control group will be placed.

Blinding (investigator's opinion)

Single blinded

Blinding description

A random sequence is produced by a statistics and methodology consultant who does not have access to patients, and only he knows what is in each number.

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

Shahryar

City

Gorgan

Province

Golestan

Postal code

4913983635

Approval date

2022-01-30, 1400/11/10

Ethics committee reference number

IR.GOUMS.REC.1400.386

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

teeth shifting

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Interleukin 1 & 6 before and two weeks later in the patients consuming curcumin mouthwash

Timepoint

Measurement of Interleukin1 & 6 in the study baseline (before treatment beginning) and 2 weeks after starting fixed orthodontic treatment

Method of measurement

Enzyme-linked Immunosorbent Assay (ELISA test)

2**Description**

Interleukin 1 & 6 before and two weeks later in the group of patients consuming chlorhexidine mouthwash

Timepoint

Measurement of Interleukin 1 & 6 in the study baseline (before treatment beginning) and 2 weeks after starting fixed orthodontic treatment

Method of measurement

Enzyme-linked Immunosorbent Assay (ELISA test)

3

Description

Interleukin 1 & 6 before and two weeks after in the group consuming curcumin + chlorhexidine mouthwash

Timepoint

Measurement of Interleukin 1 & 6 in the study baseline (before treatment beginning) and 2 weeks after starting fixed orthodontic treatment

Method of measurement

Enzyme-linked Immunosorbent Assay (ELISA test)

4

Description

Interleukin 1 & 6 before and two weeks after in the group of patients consuming normal saline mouthwash

Timepoint

Measurement of Interleukin 1 & 6 in the study baseline (before treatment beginning) and 2 weeks after starting fixed orthodontic treatment

Method of measurement

Enzyme-linked Immunosorbent Assay (ELISA test)

Secondary outcomes

1

Description

Comparison of differences in Interleukin 1 & 6 concentration before and two weeks later between two groups of patients using mouthwash containing curcumin and chlorhexidine

Timepoint

before treatment and 2 weeks after starting fixed orthodontic treatment

Method of measurement

ELISA (enzyme-linked immunosorbent assay)

2

Description

Comparison of difference in Interleukin1 & 6 concentration before and two weeks later between two groups of patients using mouthwash containing curcumin and curcumin + chlorhexidine

Timepoint

before treatment and 2 weeks after starting fixed orthodontic treatment

Method of measurement

ELISA (enzyme-linked immunosorbent assay)

3

Description

Comparison of differences in Interleukin1 & 6 concentration before and 2 weeks later between 2 groups of patients using mouthwash containing curcumin and normal saline

Timepoint

before treatment and 2 weeks after starting fixed orthodontic treatment

Method of measurement

ELISA (enzyme-linked immunosorbent assay)

4

Description

Comparison of differences in Interleukin1 & 6 concentration before and 2 weeks later between 2 groups of patients using mouthwash containing chlorhexidine and curcumin+ chlorhexidine

Timepoint

before treatment and 2 weeks after starting fixed orthodontic treatment

Method of measurement

ELISA (enzyme-linked immunosorbent assay)

5

Description

Comparison of differences in Interleukin1 & 6 concentration before and 2 weeks later between 2 groups of patients using mouthwash containing chlorhexidine and normal saline

Timepoint

before treatment and 2 weeks after starting fixed orthodontic treatment

Method of measurement

ELISA (enzyme-linked immunosorbent assay)

Intervention groups

1

Description

Intervention group 1: 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. Khorram 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 2: In this group, patients are asked to mix 20 drops of 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 3: In this group, patients are asked to mix 20 drops of nano-curcumin 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 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 Naghavihosseini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Vahid Khor

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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

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

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

Dentistry

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Position

Assistant professor

Latest degree

Specialist

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Person responsible for updating data

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Position

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Latest degree

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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