

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of curcumin _ ginger mouth wash effect on salivary MMP-8 levels in chronic periodontitis

Protocol summary

Study aim

Comparison of the effect of scaling and root planing alone and scaling and root planing with curcumin-ginger mouthwash on MMP-8 concentration in saliva

Design

randomized ,double blinded, parallel group

Settings and conduct

30 referrals to the periodontology department of Zanjan dental school in the year 1397 with moderate to severe chronic generalized periodontitis and probe depth > 4mm in at least 2 regions are selected to participate in the study. Full verbal explanation and written consent and health education is done. Patients are randomly divided into two groups (case and control) . Unstimulated saliva samples collected from patients. Then for all patients complete treatment includes scaling and root planing done. Patients in the study group will receive curcumin-ginger mouthwash and Patients in the control group will receive a placebo . patients will be asked to take 2 ml of mouthwash 2 times a day for 1 minute for 2 weeks after brushing. Two weeks after treatment of scaling , non-stimulated saliva samples are collected again. Salivary MMP-8 levels are compared at the start and end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients older than 30 years 2. Patients with moderate to severe chronic periodontitis and probe values > 4mm 3. Patients with at least 20 teeth in the mouth No entry criteria: 1. History of Systemic Disease 2. Pregnant or lactating women 3. History of antibiotic prophylaxis in the 6 months before study or use of antibiotics in the last 3 months 4. Patients with oral breathing 5. Patients with orthodontic appliances or dental prosthodontics 6. Patients with harmful habits such as smoking 7. People allergic to turmeric or ginger

Intervention groups

The intervention consisted of curcumin-ginger mouthwash in the study group and placebo mouthwash

in the control group

Main outcome variables

Reduction in salivary MMP8

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180516039682N1**

Registration date: **2018-11-06, 1397/08/15**

Registration timing: **retrospective**

Last update: **2018-11-06, 1397/08/15**

Update count: **0**

Registration date

2018-11-06, 1397/08/15

Registrant information

Name

Raheleh Akhavan rasoolzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3314 8101

Email address

r.rasoolzadeh@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-10, 1397/03/20

Expected recruitment end date

2018-09-11, 1397/06/20

Actual recruitment start date

2018-05-23, 1397/03/02

Actual recruitment end date

2018-08-24, 1397/06/02
Trial completion date
2018-08-24, 1397/06/02

Scientific title
Evaluation of curcumin _ ginger mouth wash effect on salivary MMP-8 levels in chronic periodontitis

Public title
Evaluation of curcumin _ ginger mouth wash effect on salivary MMP-8 levels in chronic periodontitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
patients older than 30 years Patients with chronic moderate to severe periodontitis and probing depth > 4mm Patients with at least 20 teeth in the mouth

Exclusion criteria:
History of Systemic Disease Pregnant or lactating women History of antibiotic prophylaxis 6 months prior to study or use of antibiotics in the last 3 months Patients with mouth breathing Patients with orthodontic appliances or dental prosthodontics Patients with harmful habits such as smoking People allergic to turmeric or ginger

Age
From **30 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
Unstimulated saliva sample
Actual sample size reached: **30**
More than 1 sample in each individual
Actual sample size in each individual: **2**
Unstimulated saliva sample

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization,Each patient was assigned one number. Then, using a random number table, each number was placed in one of the intervention group(curcumin- ginger mouthwash) or control group (placebo mouthwash).

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients were blinded to placebo or curcumin-ginger mouthwash. The outcome evaluator (immunologic kit checker) was blinded as well.

Placebo
Used

Assignment

Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences

Street address
Central Station of Zanjan University of Medical Sciences-The Beginning of the Islamic Republic Boulevard -Azadi Square-Zanjan

City
Zanjan

Province
Zanjan

Postal code
4515613191

Approval date
2018-03-13, 1396/12/22

Ethics committee reference number
IR.ZUMS.REC.1396.344

Health conditions studied

1

Description of health condition studied
generalized chronic periodontitis

ICD-10 code
K05.32

ICD-10 code description
Chronic periodontitis, generalized

Primary outcomes

1

Description
level of salivary mmp-8

Timepoint
Measurement of salivary mmp-8 at the beginning of the study (before the intervention) and 14 days after the start of mouthwash use

Method of measurement
human saliva mmp-8 Elisa kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Scaling and root planning, curcumin - ginger mouthwash for 2 weeks

Category

Treatment - Drugs

2

Description

Control group : Scaling and root planning placebo mouthwash twice a day for 2 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan Dental School

Full name of responsible person

Rahele akhavan rasool zadeh

Street address

13 Ave, Mahdavi Blvd, shahrak karmandan , dentistry univercity

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R.rasoolzadeh@zums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Alireza Shoghli

Street address

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pr@zums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Raheleh Akhavan rasoolzadeh

Position

Associate 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

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Position

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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

No - There is not 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

No - There is not 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

Not applicable

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

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Latest degree

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