

# 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

#### City

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#### Province

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#### Phone

+98 24 3314 8101

#### Email

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

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

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#### Province

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#### Phone

+98 24 3342 4771

#### Email

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

#### Name of organization / entity

Zanjan University of Medical Sciences

#### Full name of responsible person

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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**

Raheleh Akhavan rasoolzadeh

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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