

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Evaluation of curcumin \_ ginger mouth wash effect on salivary IL-1B 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 IL-1b 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 IL\_1B 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

Change in salivary IL\_1B level

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180516039682N2**

Registration date: **2018-11-16, 1397/08/25**

Registration timing: **retrospective**

Last update: **2018-11-16, 1397/08/25**

Update count: **0**

##### Registration date

2018-11-16, 1397/08/25

##### 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 IL-1B levels in chronic periodontitis

**Public title**  
Evaluation of curcumin \_ ginger mouth wash effect on salivary IL-1B 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**

2018-07-03, 1397/04/12

### **Ethics committee reference number**

IR.ZUMS.REC.1397.066

## **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 IL-1b

### **Timepoint**

Measurement of salivary IL-1b at the beginning of the study (before the intervention) and 14 days after the start of mouthwash use

### **Method of measurement**

human IL-1b ELISA

## **Secondary outcomes**

empty

## **Intervention groups**

## 1

### Description

Intervention group: Scaling and root planning, curcumin - ginger mouthwash twice a day for 2week

### Category

Treatment - Drugs

## 2

### Description

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

### 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 University

#### City

Zanjan

#### Province

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#### Postal code

4515613191

#### 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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#### Postal code

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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

#### Street address

13 Ave, Mahdavi Blvd, Shahrak Karmandan , dentistry university

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Zanjan University of Medical Sciences

#### Full name of responsible person

Raheleh Akhavan rasoolzadeh

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## 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**

Dentistry

**Street address**

13 Ave, Mahdavi Blvd, shahrak karmandan , dentistry  
university

**City**

Zanjan

## 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 further information

**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**

Not applicable