

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

**To evaluate effect of Iranian Traditional mouth rinse on controlling diabetic gingivitis and comparing it with Chlorhexidine among patients of Motahhari Clinic of shiraz in 2014.**

### Protocol summary

#### Summary

This is a triple blinded randomized clinical trial by which we want to evaluate the effect of an Iranian Traditional mouth rinse on treatment of diabetic gingivitis and compare it with chlorhexidine (2%). Among diabetic patients who refer to Motahhari clinic of Shiraz University of Medical Sciences 80 volunteers who have gingivitis and aged between 20 to 65 years old and fulfill other including criteria, are selected and randomly distributed into intervention or control groups. Then all the patients are under gone a training panel about mouth hygiene and receive a pack of a toothbrush, a toothpaste, a dental floss and a mouth rinse. They are asked to return after 2 weeks for the second evaluation and taking tooth bleaching. The demographic and general information of all participants are taken and the primary outputs (plaque index and bleeding on probe) are measured at the beginning, after 2 weeks and after 4 weeks. All the examinations are done by one person and as told before; patients, practitioner and statistical manager are blind about the intervention.

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2014071518490N1**  
Registration date: **2014-09-16, 1393/06/25**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

#### Registration date

2014-09-16, 1393/06/25

#### Registrant information

Name

Massih Sedigh Rahimabadi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

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**Email address**

sedighrm@sums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice Chancellor for research of Shiraz University of Medical Sciences

**Expected recruitment start date**

2014-07-21, 1393/04/30

**Expected recruitment end date**

2014-11-21, 1393/08/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

To evaluate effect of Iranian Traditional mouth rinse on controlling diabetic gingivitis and comparing it with Chlorhexidine among patients of Motahhari Clinic of shiraz in 2014.

**Public title**

To evaluate effect of Iranian Traditional mouth rinse on gingival bleeding of diabetic patients.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Controlled diabetes (FBS<130 or Hg A1C<7); Presence of Gingivitis; Having at least 20 teeth;

Not to have any history of hypersensitivity; Age between 20 to 65; Not to smoke more than 2 cigarette per day; Not to have any systemic diseases like; liver or rheumatologic diseases; Agreement to participate in the study. Exclusion criteria: uncontrolled diabetes (FBS>130 or Hg A1C>7); Absence of Gingivitis; Having less than 20 teeth; having history of hypersensitivity; Age less than 20 or above 65; Smoke more than 2 cigarette per day; Having systemic diseases like; liver or rheumatologic diseases; Not agree to participate in the study.

#### Age

From **20 years** old to **65 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **80**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Triple blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

### 1

#### Registry name

Clinicaltrials.gov

#### Secondary trial Id

NCT02227485

#### Registration date

2014-08-01, 1393/05/10

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Vice chansellor for research affair of Shiraz University of Medical Sciences

##### Street address

Shiraz University of Medical Sciences, Zand Ave.

##### City

Shiraz

##### Postal code

#### Approval date

2014-07-01, 1393/04/10

#### Ethics committee reference number

CT93747064

## Health conditions studied

### 1

#### Description of health condition studied

Gingivitis

#### ICD-10 code

K05.0, K05

#### ICD-10 code description

Acute and chronic gingivitis

## Primary outcomes

### 1

#### Description

Plaque index

#### Timepoint

Every 2 weeks for one month

#### Method of measurement

Exam

### 2

#### Description

Bleeding Index

#### Timepoint

Every 2 weeks for one month

#### Method of measurement

exam

## Secondary outcomes

### 1

#### Description

Drug side effects

#### Timepoint

After 2 weeks

#### Method of measurement

History taking and Exam

### 2

#### Description

Satisfaction of patients

#### Timepoint

After 2nd week

#### Method of measurement

By VAS

## Intervention groups

### 1

#### Description

Control group: Chlorhexidine (2%) mouth rinse, 10 ml for 2 minutes every night for 2 weeks.

#### Category

Treatment - Drugs

## 2

### Description

Intervention: Traditional mouth rinse, 10 ml for 2 minutes every night for 2 weeks.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Motahhari clinic of Shiraz University of Medical Sciences

##### Full name of responsible person

Massih Sedigh Rahimabadi

##### Street address

Motahhari clinic, Namazi sq.

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellery of research and technology, Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Ali Sahmeddini

##### Street address

Vice Chancellery of research and technology, Shiraz University of Medical Sciences, Zand Ave.

##### City

Shiraz

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Vice Chancellery of research and technology, Shiraz University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

empty

##### Domestic or foreign origin

empty

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Faculty of Iranian Traditional Medicine

##### Full name of responsible person

Sedigh Rahimabadi Massih

##### Position

PhD Student

##### Other areas of specialty/work

##### Street address

Imam Hasan dormitory, Dejban st.

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##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Faculty of Medicine

##### Full name of responsible person

Dr. Mesbah Shams

##### Position

Associate professor of Endocrine and Metabolic diseases

##### Other areas of specialty/work

##### Street address

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## Person responsible for updating data

#### Contact

##### Name of organization / entity

Iranian Traditional Medicine

##### Full name of responsible person

Mahsa Rostami Chijan

##### Position

Student

##### Other areas of specialty/work

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mahsa\_59\_2007@yahoo.com

**Web page address**

## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*