# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## A clinical comparison between oral irrigation with Echinacea extract as mouthwash and chlorhexidine (0.12%) in chronic periodontitis patients.

## Protocol summary

**Study aim**

goal: Comparison of the clinical effects of oral irrigation with Echinacea extract and Chlorhexidine as mouthwash on patients with chronic periodontitis.

**Design**

This is a double-blind controlled clinical trial study with 3 parallel groups using 3 different solutions.

**Settings and conduct**

Patients will be instructed to rinse for 30 seconds with 10 ml of undiluted mouth rinse once a day at night , for 28 days and to refrain from eating or drinking for 1 hour afterwards. Bass method will be taught to all patients. Also they will be instructed not to use any other dental hygiene products during the study period. Information gathering: The following procedure will be carried out for all patients, 1. Measuring Pocket depth 2. Bleeding index 3. Plaque index 4. Gingival index These clinical parameters will be measured before scaling and root planning and four weeks later at the follow-up session. Clinical examination and data gathering will be performed by a single practitioner who is blind to the groups. Complete scaling and root planning by cavitron and curette will be done for all the patients after the first measurements.

**Participants/Inclusion and exclusion criteria**

30 patients attending to the Department of Periodontology with chronic periodontitis. Inclusion criteria: 1-Presence of minimum of 22 teeth. 2-Moderate or severe chronic periodontitis. Exclusion criteria: 1-Patients with history of adverse reaction to chlorhexidine. 2-Antibiotic therapy during last 2 months. 3-Periodontal treatment during last 6 months. 4-Diabetes. 5-Pregnancy. 6-Lactation. 7-Tooth brushing more than 4 time. 8-Smoking

**Intervention groups**

Echinacea mouthwash will be given to the first group, CChlorhexidine will be given to the second group, and distilled water will be given to the third group.

**Main outcome variables**

Pocket depth Bleeding index Plaque index Gingival index

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20190813044525N1**
Registration date: **2019-09-14, 1398/06/23**
Registration timing: **retrospective**

Last update: **2019-09-14, 1398/06/23**
Update count: **0**

**Registration date**

2019-09-14, 1398/06/23

**Registrant information**

**Name**

Mohammad sadegh Karami

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 71 3646 6378

**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2019-08-13, 1398/05/22

**Expected recruitment end date**

2019-08-22, 1398/05/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
A clinical comparison between oral irrigation with Echinacea extract as mouthwash and chlorhexidine (0.12%) in chronic periodontitis patients.

**Public title**
Comparison between oral irrigation with Echinacea mouthwash and chlorhexidine

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Presence of minimum of 22 teeth. Moderate or severe chronic periodontitis.

**Exclusion criteria:**
Patients with history of adverse reaction to chlorhexidine. Antibiotic therapy during last 2 months. Periodontal treatment during last 6 months. Diabetes. Pregnancy. Lactation. Tooth brushing more than 4 time per day. Smoking

**Age**
No age limit

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **180**
1. Measuring Pocket depth. 2. Bleeding index. 3. Plaque index. 4. Gingival index

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Patients are randomly assigned to groups a randomly by a person who is unaware to the stud by using the random numbers system.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
same bottle will be use for all mouthwashes and a small color tag will be attach to botom of bottle. the bottle will be randomly given to patient by a third person who is blind to study.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Shiraz University of Medical Sciences

**Street address**
In front of No 58 , Daneshvaran St, Chogiah St,

**City**
Shiraz

**Province**
Fars

**Postal code**
7194786554

**Approval date**
2019-08-11, 1398/05/20

**Ethics committee reference number**
IR.SUMS.DENTAI.REC.1398.59

## Health conditions studied

### 1

**Description of health condition studied**
Chronic periodontitis

**ICD-10 code**
K05.3

**ICD-10 code description**
Chronic periodontitis

## Primary outcomes

### 1

**Description**
1. Measuring Pocket depth (PD) .

**Timepoint**
At base line and after 28 day

**Method of measurement**
William probe

### 2

**Description**
.2. Bleeding index (BI)

**Timepoint**
At base line and after 28 day

**Method of measurement**
Lenox method by probe

### 3

**Description**
3. Plaque index (PI).

**Timepoint**
At base line and after 28 day

**Method of measurement**
modified O'Leary method by disclosing agents

**4**

**Description**
4. Gingival index (GI)
**Timepoint**
At base line and after 28 day
**Method of measurement**
Loe and Sillness method

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Echinacea mouthwash (extract will be purchase from Zarband company and will be diluted with water to achieve .01% phenol as active compartment) will be given to the Intervention group.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: chlorhexidine will be given to the positive control group
**Category**
Treatment - Drugs

**3**

**Description**
Control group: distilled water will be given to the negative control group
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Periodontal department of Shiraz University of Medical Sciences dental school
**Full name of responsible person**
Hoda Sadat Banihashemi
**Street address**
Dental school,Ghas o dasht St .Shiraz.Iran
**City**
Shiraz
**Province**
Fars
**Postal code**
7195615878
**Phone**
+98 71 3626 3194
**Fax**
+98 71 3627 0325
**Email**
msk.sadegh@gmail.com
**Web page address**
http://dental.sums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
اندیشه تدبیر
**Street address**
Dental school,Ghas o dasht St .Shiraz.Iran
**City**
Shiraz
**Province**
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**Postal code**
7195615878
**Phone**
+98 71 3626 3194
**Fax**
+98 71 3627 0325
**Email**
msk.sadegh@gmail.com
**Web page address**
http://dental.sums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shiraz 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**
Shiraz University of Medical Sciences
**Full name of responsible person**
Mohammad Sadegh Karami
**Position**
Student
**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

**Contact**

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**Position**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mohammad Sadegh Karami

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## 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**

no more data

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available