

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparing the effect of Chamomile and Miswak containing dentifrice with Triclosan containing dentifrice in gingivitis patients

#### Protocol summary

##### Study aim

Survey of the effect of Chamomile and Miswak containing dentifrice on gingival indexes: Plaque index, Bleeding on probing, Pocket depth compared to Triclosan containing dentifrice in gingivitis patients.

##### Design

A single blinded; randomized; controlled clinical trial with parallel groups design of 15 patients; enrolled between October 2019 and December 2019; followed for 4 weeks

##### Settings and conduct

Sampling is carrying out in Periodontics department of Shiraz dental school. All the patients who met the inclusion criteria after obtaining a written consent will be examined and studying indexes will be recorded. They undergo scaling and oral hygiene education and divided by health care personnel into two groups randomly. The intervention group receive Chamomile and Miswak containing toothpaste and the control group received Triclosan containing toothpaste. Patients will be followed after 2 and 4 weeks and indexes will be recorded and analyzed. The main investigator and data analyzer are blinded in this study.

##### Participants/Inclusion and exclusion criteria

Gingivitis patient; No periodontitis and/or attachment loss; No periodontal pocket depth more than 3mm; Patient must be from 18 to 70 year old; At least 20 teeth without full crown restoration; Bleeding on probing index be at least 40%; No systemic disease like Diabetes or Cardiovascular disease; No intake of any particular medicine; Patients have not taken antibiotics in the past 6 months; Patients have not used mouthwash in the past 6 months; No smoking; No pregnancy

##### Intervention groups

In intervention group patients brush their teeth twice a day with soft tooth brushes and Chamomile and Miswak containing dentifrice for 4 weeks In control group patients brush their teeth twice a day with soft toothbrushes and Triclosan containing dentifrice for 4 weeks.

#### Main outcome variables

plaque index; bleeding on probing index; pocket depth

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190928044908N1**

Registration date: **2019-12-17, 1398/09/26**

Registration timing: **retrospective**

Last update: **2019-12-17, 1398/09/26**

Update count: **0**

##### Registration date

2019-12-17, 1398/09/26

##### Registrant information

##### Name

Zahra Emami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3626 3193

##### Email address

zahra\_emami63@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-06, 1398/07/14

##### Expected recruitment end date

2019-11-20, 1398/08/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparing the effect of Chamomile and Miswak containing dentifrice with Triclosan containing dentifrice in gingivitis patients

**Public title**

Effect of Chamomile and Miswak containing dentifrice on gingivitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Gingivitis patient Patient must be from 18 to 70 year old  
At least 20 teeth without full crown restoration Bleeding on probing index must be at least 40% No intake of any particular medicine Patients have not taken antibiotics in the past 6 months Patients have not used mouthwash in the past 6 months No smoking No pregnancy

**Exclusion criteria:**

Periodontitis and/or attachment loss Periodontal pocket depth more than 3mm Systemic disease like Diabetes or Cardiovascular disease

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Individuals are randomly divided into two groups based on randomized block randomization method. A random individual has been extracted based on this method from Sealedenvelope.com . We have 2 groups and 15 participants in each group being equal in size. Allocation concealment is achieved through sealed envelopes. After the baseline questionnaire is completed, eligible participants are assigned to one of the 2 study groups by opening the envelopes as they entered the study.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This is a single blinded clinical trial. As the toothpaste is given to patients by healthcare providers, researcher does not know how individuals are assigned to the intervention and control groups. And data will be analyzed through coding. Principle investigator, data collectors and outcome assessors being one person is referred as researcher. As contents of both groups are listed on the toothpaste tube participants are not

blinded.

**Placebo**

Not 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**

Shiraz dental school, Ghasrodasht Ave., Shiraz

**City**

Shiraz

**Province**

Fars

**Postal code**

7195615878

**Approval date**

2019-09-08, 1398/06/17

**Ethics committee reference number**

IR.SUMS.DENTAL.REC.1398.110

**Health conditions studied****1****Description of health condition studied**

Gingivitis

**ICD-10 code**

K05.10

**ICD-10 code description**

Chronic gingivitis, plaque induced

**Primary outcomes****1****Description**

The rate of periodontal pocket depth

**Timepoint**

Before intervention and after 2 and 4 weeks after intervention

**Method of measurement**

Periodontal probe

**2****Description**

The rate of bleeding on probing

**Timepoint**

Before intervention and 2, 4 weeks after intervention

**Method of measurement**

Periodontal probe

### 3

#### **Description**

The rate of dental plaque

#### **Timepoint**

Before intervention and 2, 4 weeks after intervention

#### **Method of measurement**

Disclosing agent

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group: Clean Key chamomile and Miswak containing dentifrice; made in Iran; Ahuradarou company. All toothpaste contents are listed on the toothpaste tube. Brush twice a day for four weeks using soft toothbrush and bass method as instructed by the researcher.

#### **Category**

Treatment - Drugs

#### 2

#### **Description**

Control group: Vi-One gum protector Triclosan containing dentifrice; Made in Iran Rojin company. All toothpaste contents are listed on the toothpaste tube. Brush twice a day using soft toothbrush and bass method as instructed by the researcher

#### **Category**

Treatment - Drugs

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shiraz dental school

##### **Full name of responsible person**

Zahra Emami

##### **Street address**

Shiraz dental school, Ghasrodasht Ave., Shiraz

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7195615878

##### **Phone**

+98 71 3626 3193

##### **Email**

zahra\_emami63@yahoo.com

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Shiraz University of Medical Sciences

##### **Full name of responsible person**

Dr. Gholamreza Hatam

##### **Street address**

Shiraz dental school, Ghasrodasht Ave., Shiraz

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7134814336

##### **Phone**

+98 71 3230 5410

##### **Email**

info@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**

Zahra Emami

##### **Position**

Assistant professor

##### **Latest degree**

Specialist

##### **Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

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Assistant professor

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## Person responsible for updating data

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**Full name of responsible person**

Zahra Emami

**Position**

Assistant professor

**Latest degree**

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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**

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**

Undecided - It is not yet known if there will be a plan to make this available