

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effectiveness of shallomin II and chlorhexidine mouthwashes in treating plaque induced gingivitis: A clinical trial and microbiologic study

#### Protocol summary

##### Study aim

Comparison of the effectiveness of shallomin II and chlorhexidine mouthwashes in treating plaque induced gingivitis: A clinical trial and microbiologic study

##### Design

The study is a parallel double-blind study. Randomization and assignment of patients to each of the two groups is done by the nurse. Two mouthwashes in the same packaging are offered to 36 patients, and the patients, presenters, and students are not aware of the type of mouthwash. The data will be analyzed by SPSS software version 22.

##### Settings and conduct

36 patients with gingivitis referred to the periodontology department of the Faculty of Dentistry, Jundishapur University of Medical Sciences, Ahvaz

##### Participants/Inclusion and exclusion criteria

1. Systemically healthy 2. The presence of more than 20 permanent teeth (except the third molar) 3. Untreated gingivitis (probing depth less than equal to 3, no clinical attachment loss, no evidence of radiographic bone loss.) 4. The percentage of areas with bleeding during probing should be more than 30%. 5. Not using antibiotics and anti-inflammatory drugs in the last three months 6. Not using any mouthwash in the last month. 7. Not using fixed orthodontic devices or prosthetics that interfere with the evaluation. 8. Not using cigarettes and alcohol 9. Do not have mental retardation 10. Do not be pregnant or breastfeeding. Exclusion criteria 1. Allergy to chlorhexidine and Shalomin II 2. Any pathology in the oral mucosa 3. Acute gingivitis

##### Intervention groups

Shalomin II herbal mouthwash: mouthwash derived from Iranian shallot, 5 ml twice a day for 30 seconds each time for two weeks Chlorhexidine mouthwash 0.2%: 5 ml each time and twice a day for 30 seconds each time for two weeks.

#### Main outcome variables

Plaque Index(Loe & Sillness): Gingival index(Sillness & loe) :Total colony count

#### General information

##### Reason for update

Editing indicators and entry criteria.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230305057627N1**

Registration date: **2023-04-17, 1402/01/28**

Registration timing: **prospective**

Last update: **2023-10-16, 1402/07/24**

Update count: **1**

##### Registration date

2023-04-17, 1402/01/28

##### Registrant information

###### Name

Neda Samie

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3320 5168

###### Email address

samie-n@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-21, 1402/02/01

##### Expected recruitment end date

2023-05-22, 1402/03/01

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effectiveness of shallomin II and chlorhexidine mouthwashes in treating plaque induced gingivitis: A clinical trial and microbiologic study

**Public title**  
Comparison of the effectiveness of shallomin II and chlorhexidine mouthwashes in treating plaque induced gingivitis

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Systemically healthy The presence of more than 20 permanent teeth (except the third molar) Untreated gingivitis (probing depth less than equal to 3, no clinical attachment loss, no evidence of radiographic bone loss.) The percentage of areas with bleeding during probing should be more than 30% Not using antibiotics and anti-inflammatory drugs in the last three months No mouthwash has been used in the past month Do not use cigarettes or alcohol Do not have mental retardation Not during pregnancy or breastfeeding  
**Exclusion criteria:**  
The presence of any pathology in the oral mucosa Acute gingivitis

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**  
Target sample size: **36**

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

**Randomization description**  
In this study the randomization will be done using random numbers table. After consultation with the statistics specialist even numbers will be considered for the intervention group and odd numbers for control group. The researcher stays on one of the numbers then the right direction which predefined to move and the numbers will be registered.

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

**Blinding description**  
Shallomin mouthwash will be made with the taste and color of used chlorhexidine mouthwash. Both mouthwashes are put in the same bottles and coded

(code 1 and 2). All coded bottles are placed in exactly the same packaging. The examiner will give each patient a package without knowing the meaning of each code and the type of bottle in each package, and after opening the package, the bottle code of each patient will be noted. During the study, the examiner and the patients will not know the type of mouthwash used. Meanwhile, patients are aware of participating in the study.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

**Street address**

Jundishapur University, Golestan, Ahvaz

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

1579461357

**Approval date**

2023-02-06, 1401/11/17

**Ethics committee reference number**

IR.AJUMS.REC.1401.519

## 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**

Gingival Index (Sillness & loe)

**Timepoint**

At the beginning of study, seventh day and fourteenth day

**Method of measurement**

Using a periodontal probe

## 2

### **Description**

Plaque Index (Loe & Sillness)

### **Timepoint**

At the beginning of study, seventh day and fourteenth day

### **Method of measurement**

Using a periodontal probe

## 3

### **Description**

Total colony count

### **Timepoint**

At the beginning of study, seventh day and fourteenth day

### **Method of measurement**

Counting and recording

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: 18 patients should use Shallomin II mouthwash twice a day for 2 weeks, each time at 5 cc for 30 seconds, and avoid eating and drinking for 30 to 45 minutes. The patient is also taught the correct method of brushing and hygiene education.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group: 18 patients should use 0.2% chlorhexidine mouthwash twice a day for 2 weeks, each time at 5 cc for 30 seconds, and avoid eating and drinking for 30 to 45 minutes. The patient is also taught the correct method of brushing and hygiene education.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Ahvaz Jundishapur Dental School

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

Neda Samie

##### **Street address**

Dental School, Dey Ave, Golestan Blvd

##### **City**

Ahvaz

##### **Province**

Khouzestan

#### **Postal code**

6135715775

#### **Phone**

+98 61 3320 5168

#### **Email**

samie-n@ajums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Ahvaz University of Medical Sciences

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

Mehrnoosh Zakerkish

##### **Street address**

Dental School, Ahvaz Jundishapur University Of Medical Sciences, Golestan Blvd

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##### **Email**

itc@ajums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

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

Reza Kaviani Nezhad

##### **Position**

Student

##### **Latest degree**

A Level or less

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

Dentistry

##### **Street address**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Neda Samie

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Reza Kaviani Nezhad

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

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## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

Part of the data, such as information about the main outcome, can be shared.

**When the data will become available and for how long**

Access starts 6 months after the results are published.

**To whom data/document is available**

Only for researcher working in academic and scientific institutions

**Under which criteria data/document could be used**

There are no conditions and all colleagues can use all the data

**From where data/document is obtainable**

Reza Kaviani Nezhad, Email adress:  
rezakv999@gmail.com

**What processes are involved for a request to access data/document**

Finally one week after requesting data or documentation

**Comments**