

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Comparison of antibacterial effect, tooth staining and taste disturbance of 0.2% and 0.12% Chlorhexidine mouth rinses in patients with Gingivitis or mild Periodontitis

#### Protocol summary

##### Summary

Aim: The use of Chlorhexidine is strongly recommended in prevention and treatment of periodontal diseases. This product unfortunately has some side effects such as extrinsic tooth staining and taste disturbance. The aim of this clinical trial is comparison of the tooth staining, taste disturbance and antibacterial effect of 0.2% with 0.12% Chlorhexidine mouthrinses. If the low dose mouthwash shows the same antibacterial effect as the higher dose with lesser side effects, it can be an appropriate substitute. Study Design: Interventional, randomized, double blind, unicenter, no placebo, cross over clinical trial. Inclusion Criteria: Patients with gingivitis or mild periodontitis. Exclusion criteria: Hypersensitivity to mouthwashes, pregnancy, nursing Period. All subjects received a complete dental prophylaxis before using either mouthwash. They were asked to use One of the Chlorhexidine mouthwashes was randomly given to the patients to use it two times a day for a 7 days period during which any mechanical plaque control was not allowed. After one week of wash out period the subjects entered the second 7 days period using the other product in the same manner. After each period, discoloration index and taste disturbance were measured. Also before and after mouthwash application, microbial plaque was obtained to microbial culture. Sample Size: Fifty-two interventions in 26 patients(18-60) without sex limitation Intervention: Utilization of mouthwashes

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013021612487N1**

Registration date: **2013-10-22, 1392/07/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-10-22, 1392/07/30

##### Registrant information

###### Name

Shirin Amini

###### Name of organization / entity

Khorasgan Branch, Islamic Azad University, Isfahan

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1535 4053

###### Email address

sh.amini@khuisf.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Investigator

##### Expected recruitment start date

2011-02-18, 1389/11/29

##### Expected recruitment end date

2012-02-19, 1390/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of antibacterial effect, tooth staining and taste disturbance of 0.2% and 0.12% Chlorhexidine mouth rinses in patients with Gingivitis or mild Periodontitis

##### Public title

Comparison of the antibacterial effect, tooth Staining and taste disturbance of two Iranian mouthrinses

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

Inclusion Criteria: The patients with gingivitis or mild periodontitis with 6 anterior teeth. Exclusion criteria: Severe periodontitis, any pathological Conditions in oral mucosal membranes, pregnancy or nursing period, application of Orthodontic appliances or partial denture, smoking, disturbed oral taste, hypersensitivity to mouthwashes.

### **Age**

From **18 years** old to **60 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **26**

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

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Crossover

### **Other design features**

Randomization: This study had two 7days periods. During these periods the subjects used one of the mouthwashes randomly. There was a wash out period between these two periods. Randomization carried out by throwing the coin in which 26 patients divided randomly to two groups each including 13 patients. The patients of one group used the 0.2% Chlorhexidine mouthwash during the first period and the patients of the second group used the 0.12% Chlorhexidine mouthwash during the first period. Blindness: this study was double blind because the mouthwashes were given to the patients in uniform bottles by another person other than the investigator. At the end of the study he was asked to mention the set up for application of these mouthwashes by the patients.

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Khorasgan Branch, Islamic Azad University

##### **Street address**

Dental School, Khorasgan Branch, Islamic Azad

University, University Boulevard, Arghavanieh Street, Eastern Jey Street, Isfahan, Iran

### **City**

Isfahan

### **Postal code**

81595158

### **Approval date**

2011-02-05, 1389/11/16

### **Ethics committee reference number**

D15/95

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

gingivitis or mild periodontitis

#### **ICD-10 code**

K05.3 K0

#### **ICD-10 code description**

Chronic gingivitis simple marginal, Chronic periodontitis simplex

## **Primary outcomes**

### **1**

#### **Description**

Bacterial count of Dental Plaque

#### **Timepoint**

before and One week after intervention

#### **Method of measurement**

Bacterial count on the Blood-Agar cultures

## **Secondary outcomes**

### **1**

#### **Description**

Tooth discoloration

#### **Timepoint**

Before and one week after intervention

#### **Method of measurement**

Tooth discoloration Index

### **2**

#### **Description**

Taste Disturbance

#### **Timepoint**

Before and one week after intervention

#### **Method of measurement**

Visual Analogue Scale by Questionnaire

## **Intervention groups**

### **1**

#### **Description**

0.2% Chlorhexidine mouthrinse, Shahrdarou, Iran. 7days twice a day 30 second, 15 mg

**Category**

Prevention

**2****Description**

0.12% Chlorhexidine mouthrinse, Emad darou, Iran.  
7days twice a day 30 second, 15 mg

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Dental School, Khorasgan Branch, Islamic Azad  
University

**Full name of responsible person**

Amini, Shirin

**Street address**

Dental School, Khorasgan Branch, Islamic Azad  
University, University Boulevard, Arghavanieh Street,  
Eastern Jey Street, Isfahan, Iran

**City**

Isfahan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Khorasgan Branch,  
Islamic Azad University

**Full name of responsible person**

Esfahanian, Vahid

**Street address**

Dental School, Khorasgan Branch, Islamic Azad  
University, University Boulevard, Arghavanieh Street,  
Eastern Jey Street, Isfahan, Iran

**City**

Isfahan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Khorasgan Branch, Islamic  
Azad University

**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**

Dental School, Khorasgan Branch, Islamic Azad  
University

**Full name of responsible person**

Amini, Shirin

**Position**

Assistant Professor/ DDS, MSc

**Other areas of specialty/work****Street address**

Dental School, Khorasgan Branch, Islamic Azad  
University, University Boulevard, Arghavanieh Street,  
Eastern Jey Street, Isfahan, Iran

**City**

Isfahan

**Postal code**

81595158

**Phone**

+98 31 1535 4053

**Fax****Email**

Sh.amini@khuisf.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad Dental School Khorasgan Branch  
(Isfahan)

**Full name of responsible person**

Amini Sedeh, Shirin

**Position**

Assistant Professor/ DDS, MSc

**Other areas of specialty/work****Street address**

Dental School, Khorasgan Branch, Islamic Azad  
University, University Boulevard, Arghavanieh Street,  
Eastern Jey Street, Isfahan, Iran

**City**

Isfahan

**Postal code**

81595158

**Phone**

+98 31 1535 4053

**Fax****Email**

Sh.amini@khuisf.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Dental School, Khorasgan Branch, Islamic Azad  
University

**Full name of responsible person**

Amini, Shirin

**Position**

Assistant Professor/ DDS, MSc

**Other areas of specialty/work**

**Street address**

Islamic Azad University Khorasgan (Isfahan) Branch,  
University Boulevard, Arghavanieh, Eastern Jay Street

**City**

Isfahan

**Postal code**

81595158

**Phone**

+98 31 1535 4053

**Fax**

**Email**

Sh.amini@khuisf.ac.ir

**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*