

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of hypochlorite sodium 0.25% and chlorhexidine 0.2% mouthwash on periodontal indices in treatment of patients with chronic gingivitis : A control clinical trial study

#### Protocol summary

##### Study aim

Evaluation and comparison of the effect of 0.25% sodium hypochlorite and 0.2% chlorhexidine on periodontal indices in patients with chronic gingivitis

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 20 patients, randomized with block method and randomization.com website

##### Settings and conduct

Patients with generalized marginal and papillary gingivitis who referred to the Periodontology Department of Mashhad Dental School are selected for the study. Patients are randomly divided into two groups. The first group of patients use 0.2% chlorhexidine mouthwash and the second group of patients use 0.25% hypochlorite mouthwash as an adjunct treatment after brushing twice a day for two weeks. Before using mouthwash and after this period, the condition of the gums is evaluated and compared between the two groups with the help of periodontal indices (PI), (MGI), (BOP). This study is double blind and data analyst and the outcome assessor are blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Generalized marginal and papillary gingivitis. Exclusion criteria: Patients with periodontitis; Presence of systemic diseases; Patients who have received antibiotics in the last 6 months; Patients with Necrotizing periodontitis; Use of medications affecting gingival enlargement; Patients with a positive history of HIV, AIDS; smoking >10 cigarettes a day

##### Intervention groups

Intervention group: Patients in this group use sodium hypochlorite mouthwash with NACLO chemical composition and concentration of 0.25% twice a day for two weeks after brushing. Control group: Patients in this

group use chlorhexidine mouthwash with C22H30CL2N10 chemical composition and a concentration of 0.2% twice a day for two weeks after brushing.

##### Main outcome variables

Bleeding On Probing Index (BOP); Modified Gingival Index (MGI); Plaque Index (PI)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200916048739N1**

Registration date: **2020-10-08, 1399/07/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-10-08, 1399/07/17**

Update count: **0**

##### Registration date

2020-10-08, 1399/07/17

##### Registrant information

##### Name

Reyhane Mousavi Neyshabouri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3881 9483

##### Email address

mousavinr931@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-06, 1399/07/15

##### Expected recruitment end date

2021-01-19, 1399/10/30  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty  
**Scientific title**  
Comparison of the effect of hypochlorite sodium 0.25% and chlorhexidine 0.2% mouthwash on periodontal indices in treatment of patients with chronic gingivitis : A control clinical trial study  
**Public title**  
The effect of 0.25% sodium hypochlorite mouthwash on gingivitis  
**Purpose**  
Treatment  
**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients with Generalized marginal and papillary gingivitis  
**Exclusion criteria:**  
Patients with periodontitis Diabetic patients , Severe systemic cardiac patients Patients who have received antibiotics in the last 6 months Patients with necrotizing periodontitis Systemic diseases that cause generalized gingivitis Patients with a positive history of HIV, AIDS Patients with tobacco usage in smoked or smokeless form Immunosuppressive drug therapy or use of medications affecting gingival enlargement  
**Age**  
From **18 years** old  
**Gender**  
Both  
**Phase**  
3  
**Groups that have been masked**  

- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **20**  
**Randomization (investigator's opinion)**  
Randomized  
**Randomization description**  
The method of randomization is block. In this method, we first specify the valume of each block. In this study, we use blocks with two items. Then we write a list of blocks and assign a number to them (AA1,BB2,AB3,BA4). Finally, random blocks will be selected by using the randomization.com website. Unit of randomization is individual.  
**Blinding (investigator's opinion)**  
Double blinded  
**Blinding description**  
Outcome Assessor: Mouthwashes are delivered to samples without name and in similar packages. A code is assigned to each sample, so the assessor makes assessments and measurements without knowing the intervention and control groups. Data Analyzer:

Information and data is sent to the assessor without the knowledge of the intervention and control group and with specific codes.

**Placebo**  
Not used  
**Assignment**  
Parallel  
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

##### Street address

Faculty of Dentistry, Mashhad University of Medical Sciences, Vakilabad Blvd

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948959

#### Approval date

2020-09-02, 1399/06/12

#### Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1399.060

## Health conditions studied

### 1

#### Description of health condition studied

Gingivitis

#### ICD-10 code

K05.1

#### ICD-10 code description

Chronic gingivitis

## Primary outcomes

### 1

#### Description

Bleeding On Probing Index (BOP)

#### Timepoint

At the beginning of the study and 14 days after starting mouthwash

#### Method of measurement

Using periodontal probe

### 2

#### Description

Modified Gingival Index (MGI)

### **Timepoint**

At the beginning of the study and 14 days after starting mouthwash

### **Method of measurement**

Visual observation

## **3**

### **Description**

Plaque Index (PI)

### **Timepoint**

At the beginning of the study and 14 days after starting mouthwash

### **Method of measurement**

Using periodontal probe, Loe and Silness method

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

### **Description**

Intervention group: Patients in this group use sodium hypochlorite mouthwash with NACLO chemical composition and concentration of 0.25% (15 millilitr), twice a day for two weeks after brushing. After using the mouthwash they should refrain from eating and drinking for about one hour.

### **Category**

Treatment - Drugs

### **2**

### **Description**

Control group: Patients in this group use chlorhexidine mouthwash with C22H30Cl2N10 chemical composition and a concentration of 0.2% (made by Iran Najo Company) 15 millilitr, twice a day for two weeks after brushing. After using the mouthwash they should refrain from eating and drinking for about one hour.

### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

### **Recruitment center**

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

Department of periodontology, Mashhad Faculty of Dentistry

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

Reyhane Mousavi Neyshabouri

#### **Street address**

Periodontology Department, Faculty of Dentistry, Vakilabad Blvd, Mashhad Town

#### **City**

Mashhad

#### **Province**

Razavi Khorasan

#### **Postal code**

9177948959

#### **Phone**

+98 51 3882 9501

#### **Fax**

+98 51 3882 9500

#### **Email**

MousaviNR931@mums.ac.ir

## **Sponsors / Funding sources**

### **1**

### **Sponsor**

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

Mashhad University of Medical Sciences

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

Reza Zare Mahmoudabadi

#### **Street address**

Faculty of Dentistry, Mashhad University of Medical Sciences, Vakilabad Blvd, Mashhad

#### **City**

Mashhad

#### **Province**

Razavi Khorasan

#### **Postal code**

9177948959

#### **Phone**

+98 51 3882 9501

#### **Fax**

+98 51 3882 9500

#### **Email**

MousaviNR931@mums.ac.ir

### **Grant name**

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

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

Yes

### **Title of funding source**

Mashhad University of Medical Sciences

### **Proportion provided by this source**

70

### **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**

Mashhad University of Medical Sciences

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

Reyhane Mousavi Neyshabouri

#### **Position**

Dentistry Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

Unit 2, No.54, 19 Samanieh Alley., 28 Saremi St.,  
Mashhad Town

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9178657335

**Phone**

+98 51 3881 9483

**Fax****Email**

MousaviNR931@mums.ac.ir

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Nahid Nasrabadi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Periodontology Department, Faculty of Dentistry,  
Vakilabad Blvd, Mashhad Town

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948959

**Phone**

+98 51 3882 9501

**Fax**

+98 51 3882 9500

**Email**

nasrabadi.nahid@gmail.com

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Reyhane Mousavi Neyshabouri

**Position**

Dentistry Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

Unit 2, No.54, 19 Samanieh Alley., 28 Saremi St.,  
Mashhad Town

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9178657335

**Phone**

+98 51 3881 9483

**Fax****Email**

MousaviNR931@mums.ac.ir

**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