Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Priodontology 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 analysor and the outcome assessor are blinde.

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 mililitr), 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 mililitr, 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