

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of hydrogen peroxide and zinc mouth-wash on periodontal indices in patients with chronic gingivitis in randomized clinical trial.

Protocol summary

Study aim

Determining and comparing the mean of periodontal indices after using hydrogen peroxide mouthwash in patients with gingivitis

Design

The samples will include 64 patients referred to the pre-ward of the dental school. After obtaining written consent, patients' teeth are first scaled and polished with ultrasonic devices. Health education is given to patients. At this time, patients are randomly divided into 4 groups, patients do not know which groups they are in and the same coverage is considered for mouthwashes. To blind in this study, use a coding system The information phase is phase 3.

Settings and conduct

This study is performed in Isfahan Dental School. Samples will be selected from patients referring to the Periodontics Department of the School. Patients are examined and indicators are recorded in a completely sterile unit at each follow-up. For blinding, mouthwashes are placed in the same cover for patients and the examiner

Participants/Inclusion and exclusion criteria

15 functional teeth at least Gingival index equal to or greater than 2 Don't use alcohol and cigarettes non-existence of systemic diseases that effect gingiva condition Don't use drugs that effect periodontal condition Non-existence of periodontal surgery or condition that effect periodontal diseases

Intervention groups

Control group: This group is considered as a positive control group It is considered and people in this group will not use mouthwash. Intervention group 1: in this group are asked to use 0.2% chlorhexidine mouthwash twice a day at a rate of 5 ml for 2 weeks. Intervention group 2: In this group, people are asked to use 5 ml of hydrogen peroxide mouthwash twice a day for 2 weeks. Intervention group 3: In this group, people are asked to use placebo mouthwash twice a day in the amount of 5

ml for 2 weeks.

Main outcome variables

Dental plaque/Probe depth /Gingival index /Gingival bleeding index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101006004877N29**

Registration date: **2021-10-07, 1400/07/15**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-07, 1400/07/15**

Update count: **0**

Registration date

2021-10-07, 1400/07/15

Registrant information

Name

Jaber Yaghini

Name of organization / entity

Isfahan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 31 1434 2136

Email address

j_yaghini@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of hydrogen peroxide and zinc mouth-wash on periodontal indices in patients with chronic gingivitis in randomized clinical trial.

Public title

Effect of hydrogen peroxide and zinc mouth-wash in reducing gingival inflammation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

15 functional teeth at least Gingivitis in gingival. (gingival index at least 2 or more) Don't use alcohol and cigarettes non-existence of systemic diseases that effect gingiva condition I Don't use drugs that effect periodontal condition Non-existence of periodontal surgery or condition that effect periodontal diseases

Exclusion criteria:

People with dental anomalies People over the age of 65 People with a history of orthodontic treatment People with a history of bleaching treatment.

Age

From **14 years** old to **64 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method is based on simple decomposition method which is done by lottery method. In this way, 44 envelopes are sealed, in which the four codes related to each of the experimental groups are prepared, and each participant randomly selects one of these envelopes and The base of the code inside the envelope is in one of the test groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In three groups that take mouthwash , mouthwash in the same battles but for reducing ignores , corks of battle manufacturing in three colors. The colors have a code that just researcher have known the codes refer to what kind of mouthwash.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, Ethics Committee

City

isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-08-23, 1400/06/01

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.262

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**

Decrease in probing death

Timepoint

In the beginning of research- 2 weeks- 6 weeks- 3 months

Method of measurement

By periodontal probe in the mid buccal tooth gingival

2**Description**

Plaque index

Timepoint

In the beginning of research- 2 weeks- 6 weeks- 3 months

Method of measurement

For indicating plaque index , using silness&leo plaque index . In this index , 0 demonstrative no microbial plaque , 1 demonstrative a thin layer of plaque in around of free marginal gingival, 2 demonstrative the medium amount of plaque in gingival sulcus and 3 demonstrative large amount of plaque in sulcus or periodontal pocket till free gingival margin.

3

Description

probing bleeding index

Timepoint

In the beginning of research- 2 weeks- 6 weeks- 3 months

Method of measurement

In this criterion, zero indicates the absence of bleeding, one indicates the presence of a specific bleeding point, two indicates the presence of isolated bleeding points in several cases or the presence of a single line of bleeding, three indicates that after probing the triangle between A tooth is immediately filled with blood, and a score of 4 in this index indicates heavy bleeding after probing, which immediately flows into the marginal sulcus.

4

Description

gingival index

Timepoint

In the beginning of research- 2 weeks- 6 weeks- 3 months

Method of measurement

To determine the gingivitis index (GI) of patients, the 4-part Leo & Silness criterion is used, in which zero indicates normal gingiva, one indicates mild inflammation (slight changes in color and mild edema with bleeding during probing), two indicates moderate inflammation. Along with edema redness and bleeding during probing and three also indicate severe inflammation with severe edema redness and ulceration and tendency to bleed simultaneously.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: This group is considered as a positive control group and people in this group will not use mouthwash.

Category

Treatment - Drugs

2

Description

Intervention group: People in this group are asked to use 0.2% chlorhexidine mouthwash twice a day at a rate of 5

ml for 2 weeks.

Category

Treatment - Drugs

3

Description

Second Intervention group: In this group, people are asked to use 5 ml of hydrogen peroxide mouthwash twice a day for 2 weeks.

Category

Treatment - Drugs

4

Description

third Intervention group: In this group, people are asked to use placebo mouthwash twice a day in the amount of 5 ml for 2 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental College of Isfahan University of Medical Sciences

Full name of responsible person

Alireza Parsapour

Street address

Shohadye Sofhe street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

alirezaparsapour10@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Faculty of Dentistry, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Nakisa Torabi Nia

Street address

Faculty of Dentistry, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code
8174673461

Phone
+98 31 3792 5512

Email
Torabinia@dnt.mui.ac.ir

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, Faculty of Dentistry, Isfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Jaber Yaghini

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, Dental School

City
Isfahan

Province
Isfahan

Postal code
8174673461

Phone
+98 31 3792 5542

Email
J_yaghini@dnt.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Jaber Yaghini

Position

Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, Dental School

City
Isfahan

Province
Isfahan

Postal code
8174673461

Phone
+98 31 3792 5564

Email
J_yaghini@dnt.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Jaber Yaghini

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, Dental School

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Province
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Phone
+98 31 3792 5542

Email
J_yaghini@dnt.mui.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