

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A clinical trial to compare the effect of Bisept mouthwash with Chlorhexidine 0.2% mouthwash on gingival inflammation and dental staining in gingivitis and mild periodontitis patients

Protocol summary

Summary

(1) Objectives: To compare the impact of Bisept mouthwash with conventional chlorhexidine 0.2% mouthwash on gingival inflammation, plaque accumulation, and tooth stain. (2) Design: This study is designed as a controlled randomized Parallel single blind clinical trial. (3) Setting and conduct: Thirty patients with gingivitis or mild periodontitis with clinical signs of erythema, edema and bleeding gums will participate in this study. Then they will be allocated in one of the two groups of test (Bisept mouthwash) and control (conventional chlorhexidine 0.2%) by simple randomization. (4) Major inclusion criteria: Systemically healthy individuals who are suffering from gingivitis or mild periodontitis with clinical signs of erythema, edema and bleeding gums; Major exclusion criteria: Smoking; Receiving mouthwash or periodontal treatment during the past three months. (5) Intervention: Each of the participants in test (Bisept mouthwash) or control (conventional chlorhexidine 0.2%) groups will use 15ml mouthwash two times daily for four weeks. The indices for gingival inflammation, plaque accumulation and dental staining will be measured at baseline, two weeks and four weeks and the values change will be compared between the two groups. (6) Main outcome measures: Gingival inflammation that will be evaluated using the Gingival Index and Bleeding Index and dental staining that is measured using Lobene stain index.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031527056N1**
Registration date: **2017-06-11, 1396/03/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-11, 1396/03/21

Registrant information

Name

Nazila Lashkarizadeh

Name of organization / entity

Kerman university of medical sciences, Dental school

Country

Iran (Islamic Republic of)

Phone

+98 34 3211 9021

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Kerman University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effect of Bisept mouthwash with Chlorhexidine 0.2% mouthwash on gingival inflammation and dental staining in gingivitis and mild periodontitis patients

Public title

An evaluation to compare Bisept mouthwash with chlorhexidine 0.2% mouthwash based on the influence on gingival inflammation and dental staining

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria are: Age 18_50 years old; The presence of plaque induced gingivitis (Gingival Index ≥ 2) or mild periodontitis (1_2 mm Clinical Attachment Loss) so that redness and edema of gingiva and bleeding on probing to be seen on clinical examination; At least 20 teeth present in the mouth (teeth with improper or extensive restorations, extensive caries and third molars would be excluded); Systemically healthy patients. Exclusion criteria are: A condition that affects immune system such as diabetes and pregnancy; The habit of smoking, alcohol or tobacco consumption; Antibiotics, anti-inflammatory and immunosuppressive drugs intake or mouthwash consumption during the last three months; The presence of removable or fixed appliances in the mouth; Periodontal treatment during the last three months.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Kerman University of Medical Sciences

Street address

Ethics Committee, Vice Chancellor for Research and Technology of University of Medical Sciences Building, First of Ebne Sina Street, Jahad Boulevard, Sommaye Cross road, Kerman

City

Kerman

Postal code**Approval date**

2016-11-12, 1395/08/22

Ethics committee reference number

IR.Kmu.REC.1395.99

Health conditions studied**1****Description of health condition studied**

Mild Chronic Periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic Periodontitis

2**Description of health condition studied**

Gingivitis

ICD-10 code

K05.1

ICD-10 code description

Chronic Gingivitis

Primary outcomes**1****Description**

Tooth Staining

Timepoint

Baseline, 2 weeks, 4 weeks

Method of measurement

Lobene stain index

2**Description**

Gingival inflammation

Timepoint

Baseline, 2 weeks, 4 weeks

Method of measurement

Modified Gingival Index

3**Description**

Gingival inflammation

Timepoint

Baseline, 2 weeks, 4 weeks

Method of measurement

Bleeding Index using periodontal probe

Secondary outcomes**1****Description**

Dental plaque accumulation

Timepoint

Baseline, 2 weeks, 4 weeks

Method of measurement

Oleary plaque Index

2

Description

dental plaque accumulation

Timepoint

4 weeks

Method of measurement

Observation _ Turesky plaque index

3

Description

side effects or discomfort

Timepoint

4 weeks

Method of measurement

question

Intervention groups

1

Description

Intervention in control group includes 15ml chlorhexidine 0.2% (standard) mouth wash twice daily for 4 weeks

Category

Treatment - Drugs

2

Description

Intervention in test group includes a15ml Bisept mouth wash twice daily for 4 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kerman dental school, Periodontology department

Full name of responsible person

Dr. Nazila Lashkarizadeh assistant professor in Periodontology department

Street address

Periodontology department, Dental school, End of Shafa street, Jomhoori Eslami Boulevard, Kerman

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Kerman University of Medical Sciences

Full name of responsible person

Dr. Abbas Pardakhti

Street address

Vice Chancellor for Research and Technology of University of Medical Sciences Building, First of Ebne Sina Street, Jahad Boulevard, Sommaye Cross road, Kerman

City

Kerman

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 and Technology, Kerman University of Medical Sciences

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

Kerman dental school

Full name of responsible person

Nazila Lashkarizadeh

Position

Specialist in periodontics _ Assistant professor in periodontics department

Other areas of specialty/work

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Person responsible for scientific inquiries

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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

Person responsible for updating data

Contact

Name of organization / entity

Kerman dental school

Full name of responsible person

Nazila Lashkarizadeh

Position