

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparative evaluation of salivary substantivity and antiplaque efficacy of mouthwashes containing chlorhexidine, cetylpyridinium chloride and Salvarora Persica in gingivitis patients

Protocol summary

Summary

The aim of this study is to evaluate the salivary substantivity and antiplaque efficacy of five mouthwashes including three different chlorhexidine in 0.2% and 0.12% concentration; and two mouthwashes containing Cetylpyridinium chloride and Persica, and also normal saline as negative control. 16 volunteers aged 18 and above; having gingivitis divided in 6 groups (Groups 1 to 4: each 3 volunteers and groups 4 and 5: 2 each) participated in this study. Volunteers in 6 groups will use all the mouthwashes in both parts of the study in a cross over design with washout period of 10 days. will take part in Upon obtaining written consent; for the first part of study, 1cc of unstimulated saliva will be collected at base line and 30 seconds, 1, 3, 5 and 7 hours after single use of 10cc of mouth wash and evaluate for bacterial vitality by Live Dead Backlight Fluorescence kit (Invitrogen, U.S.A). Live and dead bacteria upon absorbing coloring agent to DNA will be appeared in green and red respectively under microscope and will be counted. Upon completion of first part in all groups, for clinical evaluation, after oral prophylaxis, they will be asked to abstain from all plaque control measures and just use the allocated mouthwash, 10cc twice daily for four days. After 4 days amount of plaque of the volunteers who abstain from all hygienic method for 12-18 hours will be measured with Turesky plaque index.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204289582N1**
Registration date: **2013-12-02, 1392/09/11**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-02, 1392/09/11

Registrant information

Name

Mahmood Ghasemi

Name of organization / entity

Dental unit, Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Deputy of Research; Dental Unit; Tehran Islamic Azad University

Expected recruitment start date

2012-12-06, 1391/09/16

Expected recruitment end date

2014-04-01, 1393/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of salivary substantivity and antiplaque efficacy of mouthwashes containing chlorhexidine, cetylpyridinium chloride and Salvarora Persica in gingivitis patients

Public title

Effect of mouthwash on gingival disease

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria; 18 years and above; minimum of 24 teeth; no partial or fixed prosthesis and not under orthodontic treatment; no gingival sulcus deeper than 3mm; maximum plaque index(Turesky et al) of 2 and gingival index(Loa and Silness) of 1.5 Exclusion criteria: Age above 45 years, not smoker; no antibiotic therapy or routine antiseptic use for past 3 months; allergy to any mouth washes; no patient compliance

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

The design of study is cross over and each volunteer in each group with a washout period of 10 days for each mouthwash, will participate in both parts of the study and will use all the studied mouthwashes. The details are presented in the intervention section.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee, Deputy of Research , Dental school , Tehran Islamic Azad University

Street address

No:4; 10th Neyestan; Pasdaran Ave

City

Tehran

Postal code

Approval date

2011-10-04, 1390/07/12

Ethics committee reference number

645

Health conditions studied

1

Description of health condition studied

prevention of periodontal diseases

ICD-10 code

k05

ICD-10 code description

Gingivitis and periodontal disease

Primary outcomes

1

Description

Number of vital bacteria

Timepoint

before and after 30 second; 1; 3; 5 and 7 hours of single use of 10cc of mouthwash for 45 seconds

Method of measurement

Epifluorescence

2

Description

bacterial Plaque

Timepoint

4 days after use

Method of measurement

Turesky Plaque Index

Secondary outcomes

1

Description

Change in taste sensation

Timepoint

4 days

Method of measurement

Visual Analog Scale

2

Description

Burning sensation

Timepoint

4 days

Method of measurement

Visual analog Scale

3

Description

Presence of stain

Timepoint

4 days

Method of measurement

Observation

Intervention groups

1

Description

Group 1: First part: Salivary substantivity of mouthwashes: 1- 0.12% local Chlorhexidine mouthwash, once 10cc for 30 Sec. 2- Persica mouthwash, once 10cc for 30 Sec. 3- 0.12% Chlorhexidine Kin Gingival (Spain) mouthwash, once 10cc for 30 Sec. 4- CPC (Oral-B) mouthwash, once 10cc for 30 Sec. 5- 0.2% local Chlorhexidine mouthwash, once 10cc for 30 Sec. 6- Normal saline, once 10cc for 30 Sec. Group 1: Second part: Four days anti plaque efficacy: 1- 0.12% local Chlorhexidine mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 2- Persica mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 3- 0.12% Chlorhexidine Kin Gingival (Spain) mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 4- CPC (Oral-B) mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 5- 0.2% local Chlorhexidine mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 6- Normal saline, 10 cc for 30 Sec. twice a day and for 4 days.

Category

Treatment - Drugs

2

Description

Group 2: First part: Salivary substantivity of mouthwashes: 1- Normal saline, once 10cc for 30 Sec. 2- 0.12% local Chlorhexidine mouthwash, once 10cc for 30 Sec. 3- Persica mouthwash, once 10cc for 30 Sec. 4- 0.12% Chlorhexidine Kin Gingival (Spain) once 10cc for 30 Sec. 5- CPC (Oral-B) mouthwash, once 10cc for 30 Sec. 6- 0.2% local Chlorhexidine, once 10cc for 30 Sec. Group 2: Second part: Four days anti plaque efficacy of mouthwash. 1- Normal saline, 10 cc for 30 Sec. twice a day and for 4 days. 2- 0.12% local Chlorhexidine mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 3- Persica mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 4- 0.12% Chlorhexidine Kin Gingival (Spain) mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 5- CPC (Oral-B) mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 6- 0.2% local Chlorhexidine mouthwash, 10 cc for 30 Sec. twice a day and for 4 days.

Category

Diagnosis

3

Description

Group 3: First part: Salivary substantivity of mouthwashes: 1- Persica mouthwash, once 10cc for 30 Sec. 2- 0.12% Chlorhexidine Kin Gingival (Spain), once 10cc for 30 Sec. 3- CPC (Oral-B), once 10cc for 30 Sec. 4- 0.2% local Chlorhexidine, once 10cc for 30 Sec. 5- Normal saline once 10cc for 30 Sec. 6- 0.12% local Chlorhexidine. once 10cc for 30 Sec. Group 3: Second part: Four days anti plaque efficacy of mouthwash. 1- Persica mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 2- 0.12% Chlorhexidine Kin Gingival (Spain) mouthwash, 10 cc for 30 Sec. twice a day and for 4 days.

3- CPC (Oral-B) mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 4- 0.2% local Chlorhexidine mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 5- Normal saline, 10 cc for 30 Sec. twice a day and for 4 days. 6- 0.12% local Chlorhexidine mouthwash, 10 cc for 30 Sec. twice a day and for 4 days.

Category

Diagnosis

4

Description

Group 4: First part: Salivary substantivity of mouthwashes: 1- 0.12% Chlorhexidine Kin Gingival (Spain) once 10cc for 30 Sec. 2- CPC (Oral-B) mouthwash, once 10cc for 30 Sec., 3- 0.2% local Chlorhexidine mouthwash, once 10cc for 30 Sec. 4- Normal saline once 10cc for 30 Sec. 5- 0.12% local Chlorhexidine, once 10cc for 30 Sec. 6- Persica mouthwash once 10cc for 30 Sec. Group 4: Second part: Four days anti plaque efficacy of mouthwash. 1-0.12% Chlorhexidine Kin Gingival (Spain) mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 2- CPC (Oral-B) mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 3- 0.2% local Chlorhexidine mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 4- Normal saline, 10 cc for 30 Sec. twice a day and for 4 days. 5- 0.12% local chlorhexidine mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 6- Persica mouthwash, 10 cc for 30 Sec. twice a day and for 4 days.

Category

Diagnosis

5

Description

Group 5: First part: Salivary substantivity of mouthwashes: 1- CPC (Oral-B) mouthwash, once 10cc for 30 Sec., 2- 0.2% local Chlorhexidine mouthwash, once 10cc for 30 Sec. 3- Normal saline, once 10cc for 30 Sec. 4- 0.12% local Chlorhexidine mouthwash, once 10cc for 30 Sec. 5- Persica mouthwash, once 10cc for 30 Sec. 6- 0.12% Chlorhexidine Kin Gingival (Spain) once 10cc for 30 Sec. Group 5: Second part: Four days anti plaque efficacy of mouthwash. 1- CPC (Oral-B) mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 2- 0.2% local Chlorhexidine mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 3- Normal saline, 10 cc for 30 Sec. twice a day and for 4 days. 4- 0.12% local Chlorhexidine mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 5- Persica mouthwash, 10 cc for 30 Sec. twice a day and for 4 days.

Category

Diagnosis

6

Description

Group 6: First part: Salivary substantivity of mouthwashes: 1- 0.2% local chlorhexidine mouthwash, once 10cc for 30 Sec. 2- Normal saline, once 10cc for 30 Sec. 3- 0.12% local Chlorhexidine mouthwash, once 10cc for 30 Sec. 4- Persica mouthwash, once 10cc for 30 Sec.

5- 0.12% Chlorhexidine Kin Gingival (Spain) mouthwash, once 10cc for 30 Sec. 6- CPC (Oral-B) mouthwash, once 10cc for 30 Sec. Group 5: Second part: Four days anti plaque efficacy of mouthwash. 1- 0.2% local Chlorhexidine mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 2- Normal saline, 10 cc for 30 Sec. twice a day and for 4 days. 3- - 0.12% local Chlorhexidine mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 4- Persica mouthwash, 10 cc for 30 Sec. twice a day and for 4 days. 5- 0.12% Chlorhexidine Kin Gingival (Spain) mouthwash, 10 cc for 30 Sec. twice a day and for 4 days.

Category

Diagnosis

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

Dental School, Tehran Islamic Azad University

Full name of responsible person

Mahmood Ghasemi

Street address

No:4, 10th Neyestan, Pasdaran Ave.

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

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Full name of responsible person

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Tehran

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

Yes

Title of funding source

Dental School, Tehran 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**

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Full name of responsible person

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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