Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Comparison of mouth rinse containing alcohol free chlorhexidine with a cetylpyridinium chloride in periodontal diseases

Protocol summary

Summary

Aim: clinical effectiveness of 0.05% cetylpyridinium chloride mouth rinse in patients with gingivitis as compared to non-alcoholic chlorhexidine mouth wash. Methods & Material: Twenty-four subjects, without systemic diseases, with plaque induced gingivitis will be selected for this study. The patients were treated with scaling and rootplaning at the baseline; Oral hygiene instructions were given that included brushing twice-daily, The volunteers brushed their teeth with the Bass brushing technique for at least 2 minutes, these patients were randomly ,equally divided into two groups, Group A: perform daily mouthwashes twice a day with the solution containing 10 ml of 0.05 cetylpyridinium, (Vi-one, Rojin, Cosmetic-Lab, Kurdistan -Iran), Group B: use daily mouthwashes twice a day with 10ml of the chlorhexidine(Kin Labratories, Spain), On day 0,7,15 and day 21 of each phase the Plaque Index (PI), Pocket depth(PD), Stain Index(SI) and Bleeding Index (BI) of each volunteer were measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051717587N6**
Registration date: **2014-08-28, 1393/06/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-08-28, 1393/06/06

Registrant information

Name

Amirhossein Farahmand

Name of organization / entity

Dental Branch Islamic Azad University of Tehran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Invetigator

Expected recruitment start date

2014-07-10, 1393/04/19

Expected recruitment end date

2015-04-10, 1394/01/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison of mouth rinse containing alcohol free chlorhexidine with a cetylpyridinium chloride in periodontal diseases

Public title

Randomized, Double blind clinical study alcohol free chlorhexidine with a cetylpyridinium chloride mouth rinses in periodontal diseases

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: adult patients, older than 18 years old, systemically healthy, and having at least 20 teeth. Exclusion criteria: patients with cavitated caries, no periodontal pockets larger than 4 mm, orthodontic appliances or removable prostheses, allergies to cetylpyridinium or CHX, use of antibiotics and anti-

inflammatory drugs in the past 3 months that might alter normal gingival health, oral prophylaxis outside of study; use of oral chlorhexidine products or participation in an oral rinse study within 3 months prior to baseline examination, pregnancy or nursing, smoking.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this study, the patients were randomly (Balanced Block Randomization) equal divided into two groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Dental Branch Islamic Azad University of Tehran

Street address
No4, 10th Neyestan Alley, Pasdaran Ave,Tehran, Iran

City
Tehran

Postal code
19585/175

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
483

Health conditions studied

1

Description of health condition studied
Periodontal diseases

ICD-10 code
k05.3

ICD-10 code description
Periodontal diseases

Primary outcomes

1

Description
Reduction of pocket depth

Timepoint
One month

Method of measurement
Periodontal pobe

Secondary outcomes

1

Description
Reduction of plaque index

Timepoint
One month

Method of measurement
Plaque Index (O'Leary)

2

Description
Reduction of bleeding on probing

Timepoint
One month

Method of measurement
Bleeding index (Carterand Barnes)

Intervention groups

1

Description
Group A: perform daily mouthwashes twice a day with the solution containing 10 ml of 0.05 cetylpyridinium, (Vi-one, Rojin, Cosmetic-Lab, Kurdistan -Iran).

Category
Treatment - Drugs

2

Description
Group B: use daily mouthwashes twice a day with 10ml of the non- alcoholic chlorhexidine (Kin Labratories, Spain).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Islamic Azad University, Tehran Denatl Branch

Full name of responsible person

Amirhossein Farahmand

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No4, 10th Neyestan Alley, Pasdarn Ave,Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research Council Of Dental Branch, Islamic Azad University of Tehran

Full name of responsible person

Amirhossein Farahmand

Street address

No 4, 10th Neyestan Alley, Pasdaran Ave, Tehran, Iran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research Council Of Dental Branch, Islamic Azad University of Tehran

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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Position

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Other areas of specialty/work

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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