Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of antibacterial effect, tooth staining and taste disturbance of 0.2% and 0.12% Chlorhexidine mouth rinses in patients with Gingivitis or mild Periodontitis

Protocol summary

Summary

Aim: The use of Chlorhexidine is strongly recommended in prevention and treatment of periodontal diseases. This product unfortunately has some side effects such as extrinsic tooth staining and taste disturbance. The aim of this clinical trial is comparison of the tooth staining, taste disturbance and antibacterial effect of 0.2% with 0.12% Chlorhexidine mouthrinses. If the low dose mouthwash shows the same antibacterial effect as the higher dose with lesser side effects, it can be an appropriate substitute. Study Design: Interventional, randomized, double blind, unicenter, no placebo, cross over clinical trial. Inclusion Criteria: Patients with gingivitis or mild periodontitis. Exclusion criteria: Hypersensitivity to mouthwashes, pregnancy, nursing Period. All subjects received a complete dental prophylaxis before using either mouthwash. They were asked to use One of the Chlorhexidine mouthwashes was randomly given to the patients to use it two times a day for a 7 days period during which any mechanical plaque control was not allowed. After one week of wash out period the subjects entered the second 7 days period using the other product in the same manner. After each period, discoloration index and taste disturbance were measured. Also before and after mouthwash application, microbial plaque was obtained to microbial culture. Sample Size: Fifty-two interventions in 26 patients(18-60) without sex limitation Intervention: Utilization of mouthwashes

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013021612487N1**
Registration date: **2013-10-22, 1392/07/30**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-10-22, 1392/07/30

Registrant information

Name

Shirin Amini

Name of organization / entity

Khorasgan Branch, Islamic Azad University, Isfahan

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2011-02-18, 1389/11/29

Expected recruitment end date

2012-02-19, 1390/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of antibacterial effect, tooth staining and taste disturbance of 0.2% and 0.12% Chlorhexidine mouth rinses in patients with Gingivitis or mild Periodontitis

Public title

Comparison of the antibacterial effect, tooth Staining and taste disturbance of two Iranian mouthrinses

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion Criteria: The patients with gingivitis or mild periodontitis with 6 anterior teeth. Exclusion criteria: Severe periodontitis, any pathological Conditions in oral mucosal membranes, pregnancy or nursing period, application of Orthodontic appliances or partial denture, smoking, disturbed oral taste, hypersensitivity to mouthwashes.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **26**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features
Randomization: This study had two 7days periods. During these periods the subjects used one of the mouthwashes randomly. There was a wash out period between these two periods. Randomization carried out by throwing the coin in which 26 patients divided randomly to two groups each including 13 patients. The patients of one group used the 0.2% Chlorhexidine mouthwash during the first period and the patients of the second group used the 0.12% Chlorhexidine mouthwash during the first period. Blindness: this study was double blind because the mouthwashes were given to the patients in uniform bottles by another person other than the investigator. At the end of the study he was asked to mention the set up for application of these mouthwashes by the patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Khorasgan Branch, Islamic Azad University

Street address
Dental School, Khorasgan Branch, Islamic Azad University, University Boulevard, Arghavanieh Street, Eastern Jey Street, Isfahan, Iran

City
Isfahan

Postal code
81595158

Approval date
2011-02-05, 1389/11/16

Ethics committee reference number
D15/95

Health conditions studied

1

Description of health condition studied
gingivitis or mild periodontitis

ICD-10 code
K05.3 K0

ICD-10 code description
Chronic gingivitis simple marginal,Chronic periodontitis simplex

Primary outcomes

1

Description
Bacterial count of Dental Plaque

Timepoint
before and One week after intervention

Method of measurement
Bacterial count on the Blood-Agar cultures

Secondary outcomes

1

Description
Tooth discoloration

Timepoint
Before and one week after intervention

Method of measurement
Tooth discoloration Index

2

Description
Taste Disturbance

Timepoint
Before and one week after intervention

Method of measurement
Visual Analogue Scale by Questionnaire

Intervention groups

1

Description
0.2% Chlorhexidine mouthrinse, Shahrdarou, Iran. 7days twice a day 30 second, 15 mg

Category
Prevention

2

Description
0.12% Chlorhexidine mouthrinse, Emad darou, Iran. 7days twice a day 30 second, 15 mg
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental School, Khorasgan Branch, Islamic Azad University
Full name of responsible person
Amini, Shirin
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Khorasgan Branch, Islamic Azad University
Full name of responsible person
Esfahanian, Vahid
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Dental School, Khorasgan Branch, Islamic Azad University, University Boulevard, Arghavanieh Street, Eastern Jey Street, Isfahan, Iran
City
Isfahan
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, Khorasgan Branch, 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
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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