Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

An in vitro/in vivo evaluation of the effect of chlorhexidine in combination with sodium perborate on gingivitis, plaque and tooth surface staining

Protocol summary

Summary

Introduction: The present study evaluated staining as a result of the chlorhexidine use and the role of sodium perborate in removing stains; in addition, the amount of decreases in plaque and gingival inflammation and the role of sodium perborate in chlorhexidine efficacy in removing plaque and decreasing gingival inflammation were evaluated. Materials and methods: In the present clinical trial 40 patients referring to the Department of Periodontics, who had mild-to-moderate gingivitis were randomly divided into two groups with a parallel study design and were evaluated in a double-blind scheme. At baseline the patients underwent scaling, root planing and polishing procedures. After two weeks, plaque indexes (PI), gingival indexes (GI) and bleeding indexes (BI) were determined and recorded. In the control group 0.2% chlorhexidine gluconate mouthwash was used twice in 24 hours for 30 seconds for 14 days. In the experimental group 0.2% chlorhexidine gluconate mouthwash containing 0.2% sodium perborate was used for 30 seconds. The subjects refrained from toothbrushing during this period. After 14 days the above-mentioned indexes were again determined and recorded, along with staining indexes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102245900N1**
Registration date: **2011-04-14, 1390/01/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-04-14, 1390/01/25

Registrant information

Name
Ali Zarandi

Name of organization / entity
Hamedan dental faculty

Country
Iran (Islamic Republic of)

Phone
+98 81 1825 0498

Email address
zarandi.ali@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamedan dental faculty

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2011-02-20, 1389/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An in vitro/in vivo evaluation of the effect of chlorhexidine in combination with sodium perborate on gingivitis, plaque and tooth surface staining

Public title

An evaluation of the effect of chlorhexidine in combination with sodium perborate on gingivitis, plaque and tooth surface staining

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Presence of at least 12 anterior teeth; Mild-to-moderate gingivitis, no pockets, no attachment

loss; Informed written consent form. Exclusion criteria: allergic reaction to chlorhexidine; smoking habits; history of antibiotic use in the past three months; pregnancy; movable or fixed orthodontic appliances or movable prostheses; irremovable staining (due to tetracycline or fluoride).

Age
From **20 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double 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 Hamedan University of Medical Sciences and Health Services

Street address
Vice chancellor for research, Hamedan University of Medical Sciences and Health Services, Fahmideh Street

City
Hamedan

Postal code
65178/518

Approval date
2010-02-28, 1388/12/09

Ethics committee reference number
175840/9/35/16/پ

Health conditions studied

1

Description of health condition studied
gingivitis

ICD-10 code
K05.1

ICD-10 code description
Chronic gingivitis

2

Description of health condition studied
tooth surface staining

ICD-10 code
K03.7

ICD-10 code description
Posteruptive colour changes of dental hard tissues

Primary outcomes

1

Description
staining

Timepoint
After two weeks

Method of measurement
staining index designed by Lobene

Secondary outcomes

1

Description
gingivitis + plaque

Timepoint
After two weeks

Method of measurement
plaque indexes (PI), gingival indexes (GI) and bleeding indexes (BI)

Intervention groups

1

Description
Intervention in experimental group: 0.2% chlorhexidine gluconate mouthwash containing 0.2% sodium perborate

Category
Treatment - Drugs

2

Description
Intervention in control group: 0.2% chlorhexidine gluconate mouthwash

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Hamedan dentistry faculty

Full name of responsible person

Ali Zarandi
Street address
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan dental faculty
Full name of responsible person
Ali Zarandi
Street address
Periodontics Department, Hamedan dental faculty
City
Hamedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan dental faculty
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
Hamedan dental faculty
Full name of responsible person
Ali Zarandi
Position
Post-graduate student of Periodontics
Other areas of specialty/work
Street address
Periodontics Department, Hamedan dental faculty
City
Hamedan
Postal code
Phone
+98 81 1825 0498
Fax
Email
zarandi.ali@umsha.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan Dental faculty
Full name of responsible person
Ali Zarandi
Position
Post-graduate student of Periodontics
Other areas of specialty/work
Street address
Periodontics Department, Hamedan dental faculty
City
Hamedan
Postal code
Phone
+98 81 1825 0498
Fax
Email
zarandi.ali@umsha.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Periodontics Department, Hamedan dental faculty
Full name of responsible person
Ali Zarandi
Position
Other areas of specialty/work
Street address
City
Postal code
Phone
Fax
Email
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