

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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