

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Evaluation of tooth staining by use of polyvinylpyrrolidone (pvp) in composition with Chlorhexidine

Protocol summary

Summary

The main purpose of this study was to compare stain indices following mouth washing with Chlorhexidine + PVP with Chlorhexidine. In this randomized, double blind study, 40 patients in Periodontology of Hamadan University of Medical Sciences were randomly assigned into intervention or control groups to use Chlorhexidine + PVP or Chlorhexidine mouth wash for 2 weeks, respectively. Plaque and gingival indices, bleeding on probing index, and stain index were assessed before and after the intervention and compare between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902053795N1**
Registration date: **2010-06-04, 1389/03/14**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-06-04, 1389/03/14

Registrant information

Name

Hojatollah Yousefimanesh

Name of organization / entity

Ahvaz Junishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2010-01-21, 1388/11/01

Expected recruitment end date

2010-05-22, 1389/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of tooth staining by use of polyvinylpyrrolidone (pvp) in composition with Chlorhexidine

Public title

Evaluation of tooth staining by use of polyvinylpyrrolidone (pvp) in composition with Chlorhexidine

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: no hypersensitivity to chlorhexidine and/or PVP, not using antibiotic during 3 months prior to the study, no pregnancy, having orthodontic and removable appliances, no irreversible teeth staining, without crown and restoration at 12 anterior teeth, No smoking, mild to moderate gingival inflammation without attachment loss

Age

No age limit

Gender

Both

Phase

0

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

Ethnic committee of Hamadan University of Medical Science

Street address

Hamadan University of Medical Sciences, Mardom Park, Shahid Fahmide St., Hamadan

City

Hamadan

Postal code

Approval date

2010-01-19, 1388/10/29

Ethics committee reference number

154087/9/35/16/پ

Health conditions studied

1

Description of health condition studied

mild to moderate gingivitis

ICD-10 code

K05.1

ICD-10 code description

Chronic gingivitis

Primary outcomes

1

Description

stain index (lobene index)

Timepoint

Baseline and after 2 weeks

Method of measurement

0= no stain 1= light stain 2= moderate stain 3=heavy stain

Secondary outcomes

1

Description

Bleeding on probing (BOP)

Timepoint

Baseline and after 2 weeks

Method of measurement

Code 0 = no bleeding Code 1= bleeding

2

Description

plaque index (Silness & Loe) (PI)

Timepoint

Baseline and after 2 weeks

Method of measurement

0=no plaque,1=visible with probe,2=visible with eye,3=heavy plaque interdental filled with plaque

3

Description

gingival index (Silness & Loe GI)

Timepoint

Baseline and after 2 weeks

Method of measurement

0=Normal gingiva,1=Mild inflammation: slight change in color and slight edema. No bleeding on probing, 2=Moderate inflammation: redness, edema, and glazing. Bleeding on probing ,3=edema. Ulceration. Tendency toward spontaneous bleeding.

Intervention groups

1

Description

Chlorhexidine, mouth washing with 15cc mouth wash, 2 time a day at morning and night, for two weeks

Category

Treatment - Drugs

2

Description

Chlorhexidine + PVP, mouth washing with 15cc mouth wash, 2 time a day at morning and night, for two weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan University of Medical Science /Dentistry faculty

Full name of responsible person

Parviz Torkzaban

Street address**City**

Hamadan

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

Hamadan University of Medical Sciences

Full name of responsible person

Mirzaei

Street address

Hamadan University of Medical Sciences, Mardom Park, Shahid Fahmide St., Hamadan

City

Hamadan

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

Yes

Title of funding source

Hamadan University of Medical Sciences

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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Hamadan University of Medical Sciences

Full name of responsible person

Hojjat Yoosefimanesh

Position

Resident of Periodontology

Other areas of specialty/work**Street address**

Periodontology department, Faculty Dentistry, Hamadan University of Medical Sciences

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

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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*