Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A Clinical Trial Study of the Chlorhexidine Mouthrinses with Alcohol (Hexodine) and without Alcohol (Epimax) Effect on Gingival Clinical Parameters in Choronic Gingivitis Patients

Protocol summary

Summary

Objective: The purpose of this study is to investigate the effect of Chlorhexidine mouthrinses with Alcohol (Hexodine) and without Alcohol (Epimax) on gingival parameters in gingivitis patients. Design: This study has a randomized, double-blind, with control group, single-center design. For this respect, the mouthrinse tubes are labeled into the group A and B by third person (except patients and researcher). Then the patients are assigned randomly to the group A or B by the coin tossing. Major Inclusion criteria: gingivitis periodontitis disease; age over 18 years; not having systemic disease; no periodontal treatment in the last six months. Major Exclusion criteria: other treatments for periodontal disease during the study period. Study population: patients with chronic gingivitis disease. Sample size: 32 patients. Interventions: Chlorhexidine mouthrinses with Alcohol (Hexodine); Chlorhexidine mouthrinses without Alcohol (Epimax). Intervention time: 21.06.2012. Main Outcome Measures: Changes in gingival, plaque and stain indexes after use of mouthrinses.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504244877N27**
Registration date: **2015-08-21, 1394/05/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-08-21, 1394/05/30

Registrant information

Name

Jaber Yaghini

Name of organization / entity

Isfahan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Government: Vice Chancellor of Research, School of Dentistry, Isfahan University of Medical Sciences

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2012-06-21, 1391/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical Trial Study of the Chlorhexidine Mouthrinses with Alcohol (Hexodine) and without Alcohol (Epimax) Effect on Gingival Clinical Parameters in Choronic Gingivitis Patients

Public title

Comparison of efficacy and side effects of Chlorhexidine mouthrinses with (Hexodine) and without Alcohol (Epimax)

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patients with gingivitis disease; age over 18 years; lack of systemic disease; no pregnancy; no previous periodontal treatment and systemic antibiotics therapy in the last 6 months; not being smoker. Exclusion criteria: the patient’s unwillingness to continue the treatment; being under other treatment and taking medications which may affect the result during the study.

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
A coin tossing is used for Randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar jerib St, Isfahan, Iran.

City
Isfahan

Postal code
8174673461

Approval date
2012-05-21, 1391/03/01

Ethics committee reference number
391030

Health conditions studied

1

Description of health condition studied
Gingivitis

ICD-10 code
K05.1

ICD-10 code description
Chronic gingivitis

Primary outcomes

1

Description
Gingival Index (Löe and Silness score)

Timepoint
Two weak after intervention

Method of measurement
Observation of index score

2

Description
Plaque index (o'leary)

Timepoint
Two weak after intervention

Method of measurement
Observation of index score

3

Description
Iobene stain index

Timepoint
Two weak after intervention

Method of measurement
Observation of index score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Epimax mouthwash (Non-Alcoholic Chlorhexidine 0 .12 %) made by Emad pharmaceutical Co. Instruction: 15 milliliter of mouthwash for 60 seconds, 2 times a day (every 12 hours) for 2 weeks.

Category
Treatment - Drugs

2

Description
Control group: Hexodine mouthwash (Alcoholic Chlorhexidine 0.12%) made by Donyaye Behdasht Laboratories co. Instruction: 15 milliliter of mouthwash for 60 seconds, 2 times a day (every 12 hours) for 2 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Periodontal department, School of Dentistry, Isfahan University of Medical Sciences

Full name of responsible person
Dr Jaber Yaghini

Street address
Periodontal department, School of Dentistry, Isfahan University of Medical Sciences, Hezarjerib st., Isfahan,Iran.

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor of Research, Isfahan University of Medical Sciences

Full name of responsible person
Dr Omid Savabi

Street address
Vice chancellor of Research, School of Dentistry, Isfahan University of Medical Sciences, Hezarjerib st., 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 of Research, Isfahan 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

Name of organization / entity
Periodontal department, School of Dentistry, Isfahan University of Medical Sciences

Full name of responsible person
Dr Jaber Yaghini

Position
Assistant professor

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