

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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)

##### Phone

+98 31 1434 2136

##### Email address

j\_yaghini@dnt.mui.ac.ir

##### 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 week after intervention

#### Method of measurement

Observation of index score

### 2

#### Description

Plaque index (o'leary)

#### Timepoint

Two week after intervention

#### Method of measurement

Observation of index score

### 3

#### Description

Iobene stain index

#### Timepoint

Two week 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

Assistant professor

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

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

**City**

Isfahan

**Postal code**

8174673461

**Phone**

+98 317922825

**Fax****Email**

j\_yaghini@dnt.mui.ac.ir.

**Web page address**

## 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**

## Person responsible for scientific 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****Street address**

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

**City**

Isfahan

**Postal code**

8174673461

**Phone**

+98 317922825

**Fax****Email**

j\_yaghini@dnt.mui.ac.ir

**Web page address**

## Person responsible for updating data

#### 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****Street address**

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

**City**

Isfahan

**Postal code**

8174673461

**Phone**

+98 317922825

**Fax**

**Email**

j\_yaghini@dnt.mui.ac.ir.

**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*