

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Comparison of the effects of Chlorohexidine mouthwash 0/2% and alpha-pinen containing antiplaque mouthwash on periodontal index

#### Protocol summary

##### Study aim

Comparison of the effects of Chlorohexidine mouthwash 0/2% and alpha-pinen containing antiplaque mouthwash on periodontal index

##### Design

A randomized, blind, clinucal trial with parallel group design od 60 patients

##### Settings and conduct

This research is based on 60 people who refer to the periodontics department of the dental clinic of Kurdistan University of Medical Sciences. Patients are examined and all indicators are recorded. Then, the samples are carefully examined for supragingival calculus and the absence of periodontitis. People are asked to use 15 cc of the mouthwash they received for two weeks twice a day for one minute. Before using mouthwashes and two weeks later, people are examined and clinical indicators including plaque index, gingival index (Loe and Silness) and stain index (stain index by Loben method) will be recorded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: have at least 20 permanenr teeth, nonsmokers, being healthy, plaque index less than 2 , have gingivitis Exclusion criteria: using antibiotics, dental prophylaxis during the last 3 months ,have 5 or more dental caries, pregnant or lactating women, taking anticoagulant drugs

##### Intervention groups

Patients will be randomly divided into three groups (A: chlorhexidine 0.2%; B: anti-plaque mouthwash containing alphapinen; C: control mouthwash (containing distilled water, aspartame and food coloring).

##### Main outcome variables

Plaque index ; gingival index ; stain index

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20220726055559N1**

Registration date: **2022-10-08, 1401/07/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-10-08, 1401/07/16**

Update count: **0**

#### Registration date

2022-10-08, 1401/07/16

#### Registrant information

##### Name

Shabnam Khalifehzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3362 2260

##### Email address

shabnam.kh63ii@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2022-10-07, 1401/07/15

#### Expected recruitment end date

2022-11-06, 1401/08/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the effects of Chlorohexidine mouthwash 0/2% and alpha-pinen containing antiplaque mouthwash on periodontal index

## Public title

Effect of alpha-pinen containing qntiplaque mouthwash on periodontal index

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with at least 20 permanent teeth Non-smoking patients Being systematically healthy Plaque indx > 2

Patients with gingivitis

### Exclusion criteria:

Using topical or systemic antibiotics Dental prophylaxis during the last 3 months Patients with 5 or more dental caries require immediate restorative treatment Pregnant or lactating women Taking anticoagulant medications

## Age

No age limit

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

A randomized block design is a type of experiment where participants who share certain characteristics are grouped together to form blocks, and then the treatment (or intervention) gets randomly assigned within each block. Each block has 20 participants and each block gets different mouthwash.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The mouthwash containing alphapinene and CHX 0.2% of the placebo mouthwash are poured into similar containers in order not to separate them due to their color and will be named with the letters a, b, c. Patients who have the inclusion criterias will be selected. The nature of the procedure and possible complications and risks will be fully explained, and written informed consent will be obtained from each patient. Patients will be selected by systematic sampling and randomly divided into one of three groups (group A: chlorhexidine 0.2%; group B: anti-plaque mouthwash containing alphapinen; C: placebo mouthwash (containing distilled water, aspartame and food coloring). ) Participants and health personnel will be unaware of the type of mouthwash.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kurdistan University of Medical Science

##### Street address

Kurdistan University of Medical Science, Pasdaran Ave

##### City

Sanandaj

##### Province

Kurdistan

##### Postal code

661713446

#### Approval date

2022-09-13, 1401/06/22

#### Ethics committee reference number

IR.MUK.REC.1401.208

## Health conditions studied

### 1

#### Description of health condition studied

Generalized Gingivitis

#### ICD-10 code

K06.020

#### ICD-10 code description

Generalized gingival recession, unspecified

## Primary outcomes

### 1

#### Description

Plaque index at first

#### Timepoint

14 days

#### Method of measurement

Clinical probing(silness and loe)

### 2

#### Description

Gingival index at first

#### Timepoint

14 days

#### Method of measurement

Clinical Probing(silness and loe)

### 3

#### Description

Stain index at first

#### Timepoint

14 days

## Method of measurement

Clinical( loben method)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: A this group will receive Chlorohexidine 0/2% for 14 days. They will use it twice a day for about 2 mins.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: B this group will receive an alphapinen containing anti plaque mouthwash for 14 days. They will use it twice a day for about 2 mins.

#### Category

Treatment - Drugs

### 3

#### Description

Control group: C this group will receive a placebo mouthwash containing: distilled water, aspartame, food colouring. They will use it for 14 days twice a week for about 2 min.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kurdistan University of Medical Science

##### Full name of responsible person

Elham Motallebi

##### Street address

Kurdistan University of Medical Science, Pasdaran Ave

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##### Phone

+98 87 3366 4643

##### Email

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sanandaj University of Medical Sciences

##### Full name of responsible person

Afshin maleki

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##### Phone

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Maleki@muk.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Sanandaj University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Sanandaj University of Medical Sciences

##### Full name of responsible person

Elham Motallebi

##### Position

Dentistry student

##### Latest degree

A Level or less

##### Other areas of specialty/work

Dentistry

##### Street address

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Shabnam Khalifezadeh

**Position**

Associate Profesosr

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for updating data

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**Name of organization / entity**

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**Position**

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**Email**

E.motallebi97@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available