

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Evaluation of the effectiveness of new herbal mouthwash, Hasis on periodontal indices in patients with plaque induced gingivitis: clinical trial

#### Protocol summary

##### Study aim

Determination of the Effect of New Herbal Mouth wash, Hasis as Adjunct Treatment in Gingivitis Patients

##### Design

Clinical trials with control group, double blind, number of patients: 25, phase 3

##### Settings and conduct

On the days 0 and 14, the examiner measured the indexes in the dentistry department's Pario section. Double blind The patient did not know which mouthwash was measured The analyst did not know what data was being analyzed for which mouthwash

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Dentistry student in shahid beheshti university with plaque induced gingivitis. Exclusion criteria: Pregnant patient- smoking- patient with systemic disease and diabetes- using iron supply- orthodontics therapy

##### Intervention groups

There were two samples in each patient (the study was cross-over and randomly assigned a mouthwash to be given at first to each group, in the second stage mouthwashes have changed) 1 - Intake of mouthwash 2 - Intake of chlorhexidine On Day 0, the indexes are measured and the first mouthwash is given to the patient, then the indices associated with the first mouthwash are measured on day 14, then the patient does not use any mouthwash for 2 weeks, then the second mouthwash is given to the patient. And the indicators are measured at days 0 and 14

##### Main outcome variables

Bleeding on probing. Gingival index. Peridontal Probing Depth. plaque index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180131038572N1**  
Registration date: **2019-01-24, 1397/11/04**  
Registration timing: **retrospective**

Last update: **2019-01-24, 1397/11/04**

Update count: **0**

##### Registration date

2019-01-24, 1397/11/04

##### Registrant information

###### Name

Atiyeh Farahi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2283 7194

###### Email address

atiyehfarahi1993@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-09-06, 1396/06/15

##### Expected recruitment end date

2018-09-06, 1397/06/15

##### Actual recruitment start date

2018-09-06, 1397/06/15

##### Actual recruitment end date

2018-12-21, 1397/09/30

##### Trial completion date

2018-12-21, 1397/09/30

##### Scientific title

Evaluation of the effectiveness of new herbal

mouthwash, Hasis on periodontal indices in patients with plaque induced gingivitis: clinical trial

#### Public title

Evaluation of herbal mouthwash, Hasis on plaque induced gingivitis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Dentistry student in Shahid Beheshti University with plaque induced gingivitis

##### Exclusion criteria:

Pregnant patient, smoking patient with systemic disease and diabetes, using iron supply orthodontics therapy

#### Age

From **20 years** old to **35 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Outcome assessor
- Data analyst

#### Sample size

Target sample size: **25**

More than 1 sample in each individual

Number of samples in each individual: **2**

using Hasis and chlorhexidine mouthwash, cross over

Actual sample size reached: **25**

More than 1 sample in each individual

Actual sample size in each individual: **2**

using Hasis and chlorhexidine mouthwash, cross over

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Using the coin method, the subjects were divided into two groups A and B, Group, and accordingly, the mouthwash was first assigned to each group. Then, in the second stage, by cross over method, mouthwashes have changed.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The patient did not know which mouthwash was used. Mouthwashes were blown in opaque bottles of the same type, labeled A and B. Hasis was flavored with mint (Mint did not have a curative effect on the mouthwash, it was purely flavoring), resulting in a great deal of taste with chlorhexidine. The analyst did not know what data was being analyzed for which mouthwash. Data was provided to the analyzer in the form of mouthwash data A and mouthwash data B.

#### Placebo

Not used

#### Assignment

Crossover

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti Dental School

##### Street address

Shahid Beheshti Dental School, Velenjak St. , Shahid Chamran Highway, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1983969411

#### Approval date

2017-12-19, 1396/09/28

#### Ethics committee reference number

IR.SBMU.RIDS.REC.1396.553

## Health conditions studied

### 1

#### Description of health condition studied

plaque induced gingivitis

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

periodontal probing depth

#### Timepoint

On days 0 and 7, use mouthwash

#### Method of measurement

Measure the gap between the gingival edge to the depth of the envelope by Williams Probe

### 2

#### Description

bleeding on probing

#### Timepoint

On days 0 and 7, use mouthwash

#### Method of measurement

The presence or absence of bleeding after examination with the Williams probe by observation

### 3

#### Description

plaque index

#### Timepoint

On days 0 and 7, use mouthwash

## Method of measurement

The colored surfaces visible after application of the detector solution. o'leary index: number of painted surfaces based on the presence of plaque / number of checked levels x100

## 4

### Description

Gingival Index

### Timepoint

On days 0 and 7, use mouthwash

### Method of measurement

By Observation and probing

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group:Mouthwash Formulated by Shahid Beheshti Pharmaceutical Faculty. Using for 2 weeks. Once upon a time 2 times. For 1 minute 30 minutes after brushing in the morning and night

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group:Chlorhexidine consumption is 0.2%. Cross-over, Consume for 2 weeks. Once upon a time 2 times. For 1 minute 30 minutes after brushing in the morning and night

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Pario section ,Shahid Beheshti Dental School

##### Full name of responsible person

Dr Mohammadreza Talebi

##### Street address

Shahid Beheshti Dental School, Velenjak St. , Shahid Chamran Highway,Tehran,Iran

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+98 21 2243 9982

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##### Email

Intl\_office@sbmu.ac.ir

##### Web page address

http://dentistry.sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr Mohammadreza Safavi

##### Street address

Shahid Beheshti Dental School, Velenjak St. , Shahid Chamran Highway,Tehran,Iran

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##### Phone

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+98 21 2243 9784

##### Email

Intl\_office@sbmu.ac.ir

##### Web page address

http://dentistry.sbmu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Mohammadreza Talebi

##### Position

Associate Professor

##### Latest degree

Specialist

**Other areas of specialty/work**

Dentistry

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammadreza Talebi

**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Azalea Esmaelnejad

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**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