

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Evaluation of the effect of chlorine hexidine and matrix mouthwash on saliva pH and tongue plaque

#### Protocol summary

##### Study aim

Investigating the effect of chlorhexidine and matrix mouthwash on saliva pH and tongue plaque

##### Design

Clinical, community-based practice with a cross-blind, randomized cross-sectional group

##### Settings and conduct

A number of eligible students were selected and then their saliva pH and tongue plaque levels were assessed. Two mouthwashes were given to them 1 week apart. First, the saliva pH and plaque of their tongue were measured by a pH meter as well as a pH paper before using the mouthwash, and then 5 minutes after consumption and 30 minutes after consumption were performed in the same manner until then the data were examined. The same experiment was performed on the same participants 1 week later with another mouthwash. This was done at the Azad University of Dentistry under the supervision of the supervisor.

##### Participants/Inclusion and exclusion criteria

No systemic disease, no antibiotics, no intraoral orthopedic plates, no food 1 hour before

##### Intervention groups

Control group: 20 people, each of whom had a Matrix herbal mouthwash containing chamomile plant extract, 20 cc of this mouthwash combined with 10 cc of water and consumed for one minute by Barij Essence Iran  
Intervention group: 20 people, each of whom was given 20 cc of chlorhexidine mouthwash made by Nazhu Iran Company, had a one-minute consumption period and each one was consumed once.

##### Main outcome variables

Gender age, mouthwash, systemic disease, oral and antibiotic use, radiotherapy, oral therapy plaques, primary saliva pH, primary pH of the tongue, type of mouthwash, secondary pH of the tongue, secondary pH of saliva, time

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200406046975N1**

Registration date: **2020-05-04, 1399/02/15**

Registration timing: **retrospective**

Last update: **2020-05-04, 1399/02/15**

Update count: **0**

##### Registration date

2020-05-04, 1399/02/15

##### Registrant information

##### Name

Gita Aliakbarkhani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7644 4368

##### Email address

gitaaliakbarkhani@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-21, 1398/09/30

##### Expected recruitment end date

2020-02-19, 1398/11/30

##### Actual recruitment start date

2019-12-21, 1398/09/30

##### Actual recruitment end date

2020-02-19, 1398/11/30

##### Trial completion date

2020-02-19, 1398/11/30

##### Scientific title

Evaluation of the effect of chlorine hexidine and matrix mouthwash on saliva pH and tongue plaque

#### Public title

Effects of herbal and chemical mouthwash

#### Purpose

Health service research

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

No systemic disease No antibiotics No intraoral orthodontic plaque No food 1 hour before

##### Exclusion criteria:

Having any disease in people Gum disease infectious disease Having orthodontics

#### Age

No age limit

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Investigator
- Data analyser
- Data and Safety Monitoring Board

#### Sample size

Target sample size: **40**

Actual sample size reached: **40**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Categorized refining method: Simple and appropriate method, especially in studies with small sample size and can reduce possible heterogeneity and its application method in studies in which participants are identified before the start of the study. Randomized randomization was used in which each individual with a specific disease was not considered. The study was intended to study healthy individuals. They were individually selected and studied.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Dosocore Essays: Trials that are planned in such a way that neither the people being studied nor the observers (researchers) know who is in what group. The draft author also wrote the article, and the person in charge of collecting the data kept all of these people blind in their study. They used it, but they already told the participants about the type of mouth Vieira was given a full explanation.

#### Placebo

Not used

#### Assignment

Crossover

#### Other design features

#### Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

دانشگاه دندانپزشکی آزاد تهران

##### Street address

Pasdaran ave

##### City

Tehran

##### Province

Tehran

##### Postal code

1414633771

#### Approval date

2020-02-17, 1398/11/28

#### Ethics committee reference number

IR.IAU.DENTAL.REC.1398.070.

## Health conditions studied

### 1

#### Description of health condition studied

The pH of saliva and tongue plaque

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Saliva pH

#### Timepoint

1 week

#### Method of measurement

Hanna ph meter and ph phmeter paper

### 2

#### Description

Tongue plaque ph

#### Timepoint

1 week

#### Method of measurement

Ph meter paper

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 20 people, each of whom was given 20 cc of chlorhexidine mouthwash made by Nazhu Iran Company, had a one-minute consumption period and each of them consumed once.

**Category**

Treatment - Drugs

2**Description**

Control group: 20 people, each of whom had a Matrix herbal mouthwash containing chamomile plant extract, 20 cc of this mouthwash combined with 10 cc of water and consumed for one minute by Barij Essence

**Category**

Treatment - Drugs

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Tehran Azad University Dental Branch

**Full name of responsible person**

Mahmood Ghasemi

**Street address**

Pasdaran Ave

**City**

Tehran

**Province**

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**Postal code**

1414633771

**Phone**

+98 21 2256 4571

**Email**

Mahiran99@yahoo.com

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

Tehran University of Medical Sciences

**Full name of responsible person**

Gita Aliakbarkhani

**Street address**

Pasdaran Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

1414633771

**Phone**

+98 21 2256 4571

**Email**

Gitaaliakbarkhani@gmail.com

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

No

**Title of funding source**

Gita Aliakbarkhani

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding**

Other

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

Azad University Dental Branch

**Full name of responsible person**

Mahmood Ghasemi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

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

Tehran University of Medical Sciences

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Mahmood Ghasemi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

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**Sharing plan**

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

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

The subjects were selected to include both sexes and their age

**When the data will become available and for how long**

Start access 6 months after printing results

**To whom data/document is available**

The data will only be available to researchers working at academic and research institutes, or people working in the industry can apply for it.

**Under which criteria data/document could be used**

The use of documentation is permitted for all researchers

**From where data/document is obtainable**

Islamic Azad University, Tehran Dental Unit

**What processes are involved for a request to access data/document**

The university must go through the process of receiving the documents, which takes one day

**Comments**