Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ازاد 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
Tehran
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
Pasaran Ave
City
Tehran
Province
Tehran
Postal code
1414633771
Phone
+98 21 2256 4571
Email
Mahiran99@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mahmood Ghasemi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Pasdaran Ave
City
Tehran
Province
Tehran
Postal code
1414633771
Phone

+98 21 2256 4571

Email

Mahiran99@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahmood Ghasemi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

1414633771

Phone

+98 21 2256 4571

Email

Mahiran99@yahoo.com

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