

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparative study of the effect of three mouthwashes Alphadent Daily, Vi-One General and Vi-One Chlorhexidine on the level of salivary Streptococcus Mutans

Protocol summary

Study aim

Determination of the effect of mouthwashes Alphadent Daily, Vi-One General and Chlorhexidine Vi-One on the level of salivary Streptococcus Mutans. Determination of the average age in the studied groups. Determination of the frequency distribution of gender in the studied groups. Comparison of the level of salivary Streptococcus Mutans in three groups before and after the intervention. Determination of the level of salivary Streptococcus Mutans in three groups before and after the intervention.

Design

The number of 90 students of Sanandaj Dental School will be divided into 3 groups of 30 people by simple random method and using random blocks. The study will be conducted as a randomized, single-blind, phase 3 interventional study.

Settings and conduct

The place of intervention will be Sanandaj School of Dentistry. The one-sided blind intervention will be done by blinding the participants using unlabeled containers. Bacterial colony counting will be done in the microbiology laboratory of Sanandaj University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Students of Sanandaj Dental Faculty with informed consent to participate in the intervention. Exit conditions: Having dry mouth. Use of orthodontic and prosthodontic appliances. Any systemic disease such as diabetes. Any oral soft tissue lesions. Any composite restoration in the mouth.

Intervention groups

From all the participants, 1 ml of unstimulated saliva samples will be collected. The first group will receive Alphadent Daily mouthwash, the second group will receive Vi-One General mouthwash, and the third group will receive Vi-One Chlorhexidine mouthwash. All members will rinse the mouthwash for 60 seconds and remove it

from the mouth every night after brushing. After fourteen days, saliva sampling will be done again.

Main outcome variables

reduction in salivary Streptococcus Mutans level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240219061051N1**

Registration date: **2024-03-02, 1402/12/12**

Registration timing: **registered_while_recruiting**

Last update: **2024-03-02, 1402/12/12**

Update count: **0**

Registration date

2024-03-02, 1402/12/12

Registrant information

Name

Zahra Asgari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3366 8770

Email address

z1121377@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-28, 1402/12/09

Expected recruitment end date

2024-03-12, 1402/12/22

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of the effect of three mouthwashes Alphadent Daily, Vi-One General and Vi-One Chlorhexidine on the level of salivary Streptococcus Mutans

Public title
Assessment of the effect of mouthwashes Alphadent, Vi-One General and Chlorhexidine on salivary Streptococcus

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
To be the student of Sanandaj dentistry faculty. To have informed consent to enter the intervention.
Exclusion criteria:
Having xerostomia. Antibiotic therapy in the past month. Any systemic diseases such as Diabetes.. Any composite filling in oral cavity. Using orthodontic or prosthodontic appliances. Flouridetherapy in the past month. Any oral soft tissue lesions.

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The number of 90 students of Sanandaj Dental Faculty are divided into groups of 30 students in a simple random manner using random blocks.

Blinding (investigator's opinion)
Single blinded

Blinding description
In the single-blind intervention, mouthwashes in identical bottles without labels will be delivered to volunteers participating in the intervention.

Placebo
Not 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 Sciences

Street address

Pasdaran Blvd.

City

Sanandaj

Province

Kurdistan

Postal code

66179-13446

Approval date

2024-01-29, 1402/11/09

Ethics committee reference number

1402.203

Health conditions studied

1

Description of health condition studied

dental caries

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes

1

Description

Level of Streptococcus Mutans in saliva according to the colony forming unit.

Timepoint

At the beginning of the intervention and 14 days later.

Method of measurement

Counting the number of colonies in a specific bacterial culture medium plate.

Secondary outcomes

1

Description

The level of Streptococcus mutans in saliva in terms of colony forming units.

Timepoint

At the beginning of the trial and 14 days later.

Method of measurement

Counting the bacterial colonies formed in the specific culture medium.

Intervention groups

1

Description

First Intervention group: Alfadent Daily mouthwash, containing the active ingredient Alpha-pinene, will be used once a day after brushing at night. Made by Alphadent company.

Category

Prevention

2

Description

Second Intervention group: Vi-One General mouthwash, containing the active ingredient cetylpyridinium chloride and sodium fluoride, will be used once a day after brushing at night. Made by Rojin company.

Category

Prevention

3

Description

third intervention group: Chlorhexidine Vi-One mouthwash, containing the active ingredient chlorhexidine 0.2%, will be used once a day after brushing at night. Made by Rojin company.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kurdistan University of Medical Sciences, Dentistry Faculty.

Full name of responsible person

Kavan Yaghmouri

Street address

Pasdarán Blvd.

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kavan_yaghmoori@yahoo.com

Web page address

https://www.muk.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Afshin Maleki

Street address

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kavan_yaghmoori@yahoo.com

Web page address

https://www.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

Zahra Asgari

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

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Position

Student

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A Level or less

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Person responsible for updating data

Contact

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable