Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 group 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 Alfadent 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 compposite 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
Pasdaran Blvd.
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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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Email
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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Position
Student

Latest degree
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Person responsible for updating data

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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