Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of effect of three mouthwashes Listerine, Irsha, and Vi one general on the salivary streptococcus mutans level.

Protocol summary

Study aim
Comparative study of effect of three mouthwashes Listerine, Irsha, and Vi one general on the salivary streptococcus mutans level.
Design
Clinical trial, single blind and with parallel groups
Settings and conduct
School of Dentistry, Kurdistan University of Medical Sciences
Participants/Inclusion and exclusion criteria
Clinical samples are selected from dental students of Kurdistan University of Medical Sciences. Inclusion criteria: informed consent of participants Exclusion criteria: Taking antibiotics in the last month - Performed fluoride therapy in the last month Existence of orthodontic appliques Existence of diseases with suppressed immune system and diabetes Presence of oral soft tissue lesions such as irritated fibroids, PGCG, papilloma
Intervention groups
1- listerine mouthwash, COOL MINT model 2. Vi one General mouthwash without alcohol 3- Irsha Anti-Plaque Mouthwash
Main outcome variables
Reduction of salivary streptococcus mutans

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20161019030377N1**
Registration date: **2021-12-18, 1400/09/27**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-18, 1400/09/27**
Update count: **0**
Registration date
2021-12-18, 1400/09/27

Registrant information
Name
Seyyedeh Pouya Morovati
Name of organization / entity
kurdistan university of medical sciences,school of dentistry
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-06-05, 1400/03/15
Expected recruitment end date
2021-12-22, 1400/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of effect of three mouthwashes Listerine, Irsha, and Vi one general on the salivary streptococcus mutans level.

Public title
Comparative study of effect of three mouthwashes Listerine, Irsha, and Vi one general on the salivary streptococcus mutans level.
Purpose
Treatment
Inclusion/Exclusion criteria

Inclusion criteria:
Dental Students of Kurdistan University of Medical Sciences Informed Consent
Exclusion criteria:
antibiotic consumption within recent month fluoride therapy within recent month orthodontic appliance immune- compromised condition like Diabetic patients soft tissue oral pathology like PGCG etc.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The names of all the people who are eligible to enter the research (180 people) are written on separate cards and all are placed in a container, then the people who are drawn out one by one, The research samples (90 people) are randomly divided into three groups of one, two and three. They are written with the letter A, another third with the letter B, and the other third with the letter C, and people are grouped into one, two, or three based on the letter of the selected card.

Blinding (investigator's opinion)
Single blinded

Blinding description
The present study will be single blinded and all mouthwashes are prepared into opaque bottles of the same volume without any specifications

Placebo
Not used

Assignment
Parallel

Other design features
For the first time, the clinical efficacy of Vi One mouthwash in relation to other mouthwashes in reducing salivary streptococcus mutans is being evaluated.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciences

Street address
Pasdaran Street

City
Sanandaj

Province
Kurdistan

Postal code
6617713446

Approval date
2021-01-11, 1399/10/22

Ethics committee reference number
IR.MUK.REC.1399.264

Health conditions studied

1

Description of health condition studied
salivary streptococcus mutans

ICD-10 code
K02

ICD-10 code description
Dental caries

Primary outcomes

1

Description
Reduction of salivary streptococcus mutans

Timepoint
2weeks

Method of measurement
Samples are asked to use mouthwash once a day for 2 weeks and after consuming mouthwash for at least 30 minutes to refrain from consuming any food and beverages as well as mouth washing. Saliva samples are taken from all participants before and after mouthwash. The sampling method is to ask them to rinse their mouths with saline before eating breakfast and brushing their teeth. Then 1 cc of non-stimulating saliva is collected by spitting in a sterile tube and immediately sent to the laboratory for microbial culture and measurement of Streptococcus mutans (CFU / ml).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Listeine mouthwash:Samples are asked to use this mouthwash once a day for 2 weeks and after using the mouthwash, avoid consuming any food and drink for at least 30 minutes and also to rinse the mouth. Before and after using the mouthwash, saliva sampling is performed from all participants. In this way,They are asked to rinse their mouths with saline before eating breakfast and brushing their teeth, and to rinse their contents after rinsing. 1 cc of their non-stimulated saliva is then collected by spitting into a sterile tube and immediately sent to a laboratory for

microbial culture and measurement of Streptococcus mutans (CFU / ml).

Category

Prevention

2

Description

Intervention group: Vi One general mouthwash :Samples are asked to use this mouthwash once a day for 2 weeks and after using the mouthwash, avoid consuming any food and drink for at least 30 minutes and also to rinse the mouth. Before and after using the mouthwash, saliva sampling is performed from all participants. In this way,They are asked to rinse their mouths with saline before eating breakfast and brushing their teeth, and to rinse their contents after rinsing. 1 cc of their non-stimulated saliva is then collected by spitting into a sterile tube and immediately sent to a laboratory for microbial culture and measurement of Streptococcus mutans (CFU / ml).

Category

Prevention

3

Description

Intervention group: Irsha mouthwash:Samples are asked to use this mouthwash once a day for 2 weeks and after using the mouthwash, avoid consuming any food and drink for at least 30 minutes and also to rinse the mouth. Before and after using the mouthwash, saliva sampling is performed from all participants. In this way,They are asked to rinse their mouths with saline before eating breakfast and brushing their teeth, and to rinse their contents after rinsing. 1 cc of their non-stimulated saliva is then collected by spitting into a sterile tube and immediately sent to a laboratory for microbial culture and measurement of Streptococcus mutans (CFU / ml).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

dental school ,Kurdistan university of medical sciences

Full name of responsible person

Seyyedeh Pouya Morovati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Dr Afshin Maleki

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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

Seyyedeh Pouya Morovati

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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
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