

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

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

Protocol summary

2021-12-18, 1400/09/27

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

Registrant information

Name

Seyyedeh Pouya Morovati

Name of organization / entity

kurdistan university of medical sciences,school of dentistry

Country

Iran (Islamic Republic of)

Phone

+98 87 3366 9507

Email address

morovati.p@muk.ac.ir

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: Listerine 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

Street address

Pasdaran Street

City

Sanandaj

Province

Kurdistan

Postal code

6617713446

Phone

+98 87 3366 8770

Email

pouyamorovati@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Dr Afshin Maleki

Street address

Pasdaran Street

City

Sanandaj

Province

Kurdistan

Postal code

6617713446

Phone

+98 87 3366 8770

Email

Pouyamorovati@gmail.com

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

Street address

Pasdaran Street

City

Sanandaj

Province

Kurdistan

Postal code
66177713446
Phone
+98 87 3366 8770
Email
pouyamorovati@gmail.com

Person responsible for scientific 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
Street address
Pasdaran Street
City
Sanandaj
Province
Kurdistan
Postal code
66177713446
Phone
+98 87 3366 8770
Email
pouyamorovati@gmail.com

Person responsible for updating data

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
Street address
Pasdaran Street
City
Sanandaj
Province
Kurdistan
Postal code
66177713446
Phone
+98 87 3366 8770
Email
pouyamorovati@gmail.com

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