Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of the effects of protact mouthwash with chlorhexidine on Streptococcus mutans attached to orthodontic elastic rings

Protocol summary

Study aim

This study aims to compare the antibacterial effects of Protact herbal mouthwash and chlorhexidine on Streptococcus mutans in orthodontic patients.

Design

A randomized clinical trial in the form of a randomized block with a control group, with parallel groups, double-blind on 22 patients. Choosing the type of group for each person through random allocation software 2

Settings and conduct

The study population will be patients who are candidates for fixed orthodontic treatment, referring to a private practice in Sari city, and the study site will be the Faculty of Dentistry of Mazandaran University of Medical Sciences. Sampling of patients of each group in 3 times; Mouthwash will be used before the intervention, immediately after the intervention and after 20 days of continuous use.

Participants/Inclusion and exclusion criteria

The study population will be selected from patients who are candidates for fixed orthodontic treatment referred to a private office in Sari city, who meet the entry criteria and do not meet the exit criteria of the study, during the years 1400-1401. The entry criteria will include patients without periodontitis and with proper cooperation (15 years and above). Exclusion criteria include poor patient cooperation, use of corticosteroids, sensitivity to mouthwash, or use of any antibiotic and mouthwash during the past three months for 10 consecutive days.

Intervention groups

Patients will be placed in two intervention (protact mouthwash) and control (0.2% chlorhexidine mouthwash) groups. Patients of both groups will be required to use 5 ml of their mouthwash twice a day (morning and night) for 20 days for 30 seconds to one minute and refrain from eating and drinking for an hour afterwards.

Main outcome variables

The number of Streptococcus mutans bacteria present on the elastic rings of the patients will be recorded at each stage of sampling and the data will be compared

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170502033770N3**
Registration date: **2023-06-20, 1402/03/30**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-20, 1402/03/30**
Update count: **0**

Registration date

2023-06-20, 1402/03/30

Registrant information

Name
Hodis Ehsani

Name of organization / entity
Mazandaran University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-17, 1402/03/27

Expected recruitment end date

2023-07-06, 1402/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effects of protact mouthwash with chlorhexidine on Streptococcus mutans attached to orthodontic elastic rings

Public title

The comparison of the effects of protact mouthwash with chlorhexidine on Streptococcus in orthodontic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients without periodontitis Patients with appropriate cooperation Patients with a minimum age of 15 years

Exclusion criteria:

Patients using any antibiotics and mouthwash during the last three months for 10 consecutive days Patients taking corticosteroids Patients with mouthwash allergy

Age

From **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **22**

More than 1 sample in each individual

Number of samples in each individual: **3**

Sampling of each person will be done in three stages. Once before using the mouthwash, the second time after using the desired mouthwash and in the same session, the third sampling will be done after 20 days of consecutive use of the mouthwash.

Randomization (investigator's opinion)

Randomized

Randomization description

Random block method will be used to assign samples to groups (type of mouthwash). First, the samples will be matched in terms of age, gender, periodontium condition and oral hygiene and people with similar status will be placed in a block. According to the total number of required samples (22 samples) and the number of mouthwashes, finally 11 blocks with matched samples will be considered as 2 samples in each block (number of mouthwashes). Selection of blocks and type of mouthwash for each sample will be done through random allocation software 2 and the samples will be placed in one of the groups by this software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind. In order to blind patients, therapists and researchers, mouthwashes are placed in dark-colored bottles with the same appearance with different labels and according to the recommendations of the manufacturers, the mouthwash instructions leaflet is given to the patients in identical envelopes with different labels according to the mouthwash label, and the patients are asked to use the relevant mouthwash according to the leaflet.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Khazar Blvd, Sari Faculty of Dentistry (Tooba dental clinic)

City

Sari

Province

Mazandaran

Postal code

4816895475

Approval date

2022-07-06, 1401/04/15

Ethics committee reference number

IR.MAZUMS.REC.1401.229

Health conditions studied

1

Description of health condition studied

Dental caries and gingivitis caused by Streptococcus mutans bacterial plaques

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The number of Streptococcus mutans bacteria

Timepoint

in three occasions, before consumption, immediately after consumption and after 20 consecutive days of consumption

Method of measurement

Separation and collection of elastic rings

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will be given Protact mouthwash (Daneshgar Zolang Respina pharmaceutical company) and the patients will be required to use 5 ml of their mouthwash for 30 seconds to one minute twice a day (morning and night) for 20 days. and avoid eating and drinking for an hour after that. All patients will be given the same Oral_B toothbrush and toothpaste, and they will be taught proper mechanical hygiene (at least twice a day).

Category
Treatment - Drugs

2

Description
Control group: The control group will be given 0.2% chlorhexidine mouthwash (Iran Najo Pharmaceutical Company) and the patients will be required to use 5 ml of their mouthwash for 30 seconds to one minute twice a day (morning and night) for 20 days. and avoid eating and drinking for an hour after that. All patients will be given the same Oral_B toothbrush and toothpaste, and they will be taught proper mechanical hygiene (at least twice a day).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Sari Faculty of Dentistry

Full name of responsible person
Hodis Ehsani

Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
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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
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Hodis Ehsani

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Hodis Ehsani

Position
Assistant Professor

Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document
After the completion of the project, the results will be delivered in the form of a final report and in electronic form (on a CD) to the Vice-Chancellor of Research and Faculty of Dentistry of Mazandaran University of Medical Sciences.

When the data will become available and for how long
The decision regarding access to the data will be the responsibility of the vice president of research and the Faculty of Dentistry of Mazandaran University of Medical Sciences, as well as the supervisor.

To whom data/document is available
Vice President of Research, Faculty of Dentistry, Mazandaran University of Medical Sciences and also the supervisor

Under which criteria data/document could be used
The request should be sent to the responsible person after consultation with the research team, the data will be provided to the requesting person, and it is necessary to give reference to the data owners in the articles or wherever the data is to be used, and the use of the results only It is allowed by citing its source.

From where data/document is obtainable
Vice President of Research, Faculty of Dentistry, Mazandaran University of Medical Sciences and also the supervisor

What processes are involved for a request to access data/document
A written request to the vice president of research or the Faculty of Dentistry of Mazandaran University of Medical Sciences and also obtaining the consent of the supervisor.

Comments