

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

effect of chlorhexidine-releasing elastomerics on Streptococcus mutans Levels in orthodontic patients Saliva

Protocol summary

Study aim

Determining the Effect of Chlorhexidine Releasing Elastomeric Ligatures on the Number of Streptococcus Mutants in Orthodontic Patients

Design

A randomized, double-blind, placebo-controlled clinical trial of 30 patients.

Settings and conduct

In this study, 30 patients in need of fixed orthodontic treatment referred to the dental clinic were selected. The patients were randomly divided into control and intervention groups. Normal elastomeric ligature in the control group and chlorhexidine-releasing elastomers in the intervention group were used. The study is double-blind. Participant and outcome assessor (microbiologist) and data analyzer are unaware of who is in what group and the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who need fixed orthodontic treatment
Exclusion criteria: Receive any antibiotics or other medication, fluoride treatment during the previous two weeks, any systemic illness, prosthetic or soft tissue lesions, and common caries.

Intervention groups

In the intervention group, chlorhexidine-releasing elastomerics were used. Chlorhexidine-releasing elastomeric ligatures were used twice at baseline and 28 days after baseline study.

Main outcome variables

Streptococcus mutans bacteria in saliva
Streptococcus mutans bacteria count at the surface of elastomeric ligation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181203041837N1**

Registration date: **2020-02-26, 1398/12/07**

Registration timing: **retrospective**

Last update: **2020-02-26, 1398/12/07**

Update count: **0**

Registration date

2020-02-26, 1398/12/07

Registrant information

Name

somayeh mehrabi koushki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8880 1760

Email address

somaye.mehrabi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-02, 1398/02/12

Expected recruitment end date

2019-08-19, 1398/05/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effect of chlorhexidine-releasing elastomerics on Streptococcus mutans Levels in orthodontic patients Saliva

Public title

Effect of chlorhexidine-releasing elastomerics on

Streptococcus mutans Levels in orthodontic patients
Saliva

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with fixed orthodontic treatment
Exclusion criteria:
existence of any systemic disease, Use antibiotics and other medication within two weeks before starting the study existence prosthodontic appliances, existence soft tissue lesions existence rampant caries

Age
From **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, patients in need of fixed orthodontic treatment referring to dental clinic were randomly divided into two groups of intervention and control by a non-researcher. Individuals were divided into two groups of 15 individuals, each numbered from 1 to 30, and then randomly divided into two groups using random allocation software. Information about each individual was stored in numbered envelopes that were similar in appearance.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study is a double blind study. Chlorhexidine-releasing elastomerics and conventional elastomerics were quite similar in appearance and color. Patients received their elastomeric according to the assigned number. Patients were completely unaware of the elastomeric type. Saliva samples were given to microbiologists in similar containers. The microbiologist and the statistical analyzer were unaware of what elastomeric each patient used.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of School of Dentistry, Islamic Azad University, Isfahan (Khorasgan) Branch
Street address
Islamic Azad University, Khorasgan Branch University Blvd, Arqavanieh, Jey Street Isfahan, Iran
City
Isfahan
Province
Isfahan
Postal code
81851-39998
Approval date
2018-12-12, 1397/09/21
Ethics committee reference number
IR.IAU.KHUISF.REC.1397.121

Health conditions studied

1

Description of health condition studied
dental caries

ICD-10 code
K02.9

ICD-10 code description
Dental caries, unspecified

Primary outcomes

1

Description
Colony Forming Unit (CFU) of Streptococcus mutans in saliva

Timepoint
baseline, and 7, 14, 21 and 28 days after the intervention

Method of measurement
Saliva sample collection for culture

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Orthodontic elastomers using the combination of chlorhexidine diacetate as an antibacterial agent and ethyl cellulose as the polymer. The volume of polymer used was 2%. Chlorhexidine-releasing elastomeric ligatures were used twice at baseline and 28 days after baseline study.

Category
Prevention

2

Description

Control group: conventional elastomeric ligatures were

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University (Khorasgan Branch),
Orthodontic Department

Full name of responsible person

Dr. Somayeh Mehrabi

Street address

Dental school, Isfahan Azad University (Khorasegan
branch), Arghavanieh Blvd.

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+98 31 3535 4004

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somaye.mehrabi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Amir Mansour Shirani

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Dental school, Isfahan Azad University (Khorasegan
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hshirali@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Dental school

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

Islamic Azad University

Full name of responsible person

Somayeh Mehrabi Koushki

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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No. 28 Nasr St. Valieasr Sq.

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Fax**Email**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

File of Intervention program protocol and Statistical analysis plan through the publication of the thesis or writing an article

When the data will become available and for how long

Starting 6 months after publication of results.

To whom data/document is available

Research team of this study and other clinical academic researchers who are studying in favor of these patients

Under which criteria data/document could be used

Researchers who intend to write a meta-analysis or systematic review articles are allowed to access documents

From where data/document is obtainable

Dr. Somayeh Mehrabi (somaye.mehrabi@gmail.com)

What processes are involved for a request to access data/document

The request will be responded after getting the approval of university or the Academic Institution

Comments