Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 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)

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+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

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Province

Isfehan

Postal code

۸۱۵۵۱-۳۹۹۹۸

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr Amir Mansour Shirani
Street address
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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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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 responsed after getting the approval of university or the Academic Institution

Comments