

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 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**

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

##### Street address

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

##### City

Isfahan

##### Province

Isfahan

##### Postal code

۸۱۵۵۱-۳۹۹۹۸

##### Phone

+98 31 3535 4004

##### Email

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

##### Street address

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

##### City

Isfahan

##### Province

Isfahan

##### Postal code

۸۱۵۵۱-۳۹۹۹۸

##### Phone

+98 31 3535 4053

##### Email

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

##### Street address

No. 28 Nasr St. Valieasr Sq.

##### City

Tehran

##### Province

Tehran

##### Postal code

۸۱۵۵۱-۳۹۹۹۸

##### Phone

+98 21 8880 1760

##### Fax

##### Email

somaye.mehrabi@gmail.com

## Person responsible for scientific 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

##### Street address

No. 28 Nasr St. Valieasr Sq.

##### City

Tehran

##### Province

Tehran

##### Postal code

۸۱۵۵۱-۳۹۹۹۸

##### Phone

+98 21 8880 1760

##### Fax

**Email**

somaye.mehrabi@gmail.com

**Person responsible for updating data****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

**Street address**

No. 28 Nasr St. Valieasr Sq.

**City**

Tehran

**Province**

Tehran

**Postal code**

۸۱۵۵۱-۳۹۹۹۸

**Phone**

+98 21 8880 1760

**Fax****Email**

somaye.mehrabi@gmail.com

**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**