

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Clinical evaluation of the effect of fluoride-releasing elastomeric chains on the number of Streptococcus mutans in orthodontic patients.

Protocol summary

Summary

Despite the health advantages of orthodontics on the oral and dental health, the presence of orthodontic brackets creates obstacle for patients such as increased accumulation of bacterial plaques. During fixed-treatment the absolute number of salivary Streptococcus mutans, as well as the percentage of Streptococcus mutans were increased which leads to increased occurrence of demineralized lesions and dental caries. The purpose of present study was to evaluate the efficacy of fluoride-releasing elastomeric chains in the control of Streptococcus mutans level in the saliva and surrounding the orthodontic appliances plaque. Sixty patients, who would undergoing fixed-orthodontic appliance treatment would selected and randomly divided into 2 groups of 30. patients must would in overall health situation and do not have any systemic disease In group 1 fluoride-release elastomeric chains would used and conventional elastomeric chains used in group 2. Saliva would collected On days initial, 7, 14, 28, from both groups, and bacterial plaques sample would collected on days initial, 28. At day 28, the fluoride-release and conventional elastomeric chains would removed. All samples would transferred for microbial culture in order to counting the Streptococcus mutans colonies.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201110317959N1**

Registration date: **2012-02-12, 1390/11/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-02-12, 1390/11/23

Registrant information

Name

Samaneh Sadeghy

Name of organization / entity

Post graduate student

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Office of Vice Chancellor for Research of Shiraz
University of Medical Sciences

Expected recruitment start date

2011-12-31, 1390/10/10

Expected recruitment end date

2012-01-15, 1390/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of the effect of fluoride-releasing elastomeric chains on the number of Streptococcus mutans in orthodontic patients.

Public title

Clinical evaluation of the effect of fluoride-releasing elastomeric chains on the number of Streptococcus mutans in orthodontic patients.

Purpose

Prevention

Inclusion/Exclusion criteria
The inclusion criteria are: 18-28 years old; teeth with normal size; are in overall health situation; do not use antibiotics within the previous 2 weeks. Exclusion criteria: lack of above criteria

Age
From **18 years** old to **28 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Committee on Shiraz Medical Science University

Street address
Ethical Committee on Shiraz Medical Science University; Medicine faculty; Zand Blv;

City
Shiraz

Postal code
-

Approval date
2011-12-01, 1390/09/10

Ethics committee reference number
CT-90-3596

Health conditions studied

1

Description of health condition studied
Dental caries

ICD-10 code
R19.8

ICD-10 code description

Other specified symptoms and signs involving the digestive system and abdomen

Primary outcomes

1

Description
Streptococcus mutans bacteria

Timepoint
on days 0; 7; 14; 28

Method of measurement
counting number of Streptococcus mutans colonies

Secondary outcomes

empty

Intervention groups

1

Description
study group: fluoride releasing elastomeric chains would be used

Category
Prevention

2

Description
control group: conventional elastomeric chains used

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Orthodontics, Dentistry Faculty

Full name of responsible person
Dr Samaneh Sadeghy

Street address
Dentistry Faculty; Qom abad Ave

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Office of Vice Chancellor for Research of Shiraz University of Medical Sciences

Full name of responsible person
Dr Gholam Reza Hattam

Street address
Shiraz Medical Science University; zand.blv

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Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Office of Vice Chancellor for Research of Shiraz
 University of Medical Sciences
Proportion provided by this source
 100
Public or private sector
 empty
Domestic or foreign origin
 empty
Category of foreign source of funding
 empty
Country of origin
Type of organization providing the funding
 empty

Person responsible for general inquiries

Contact

Name of organization / entity
 Orthodontic Research Center
Full name of responsible person
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
 empty
Study Protocol
 empty
Statistical Analysis Plan
 empty
Informed Consent Form
 empty
Clinical Study Report
 empty
Analytic Code
 empty
Data Dictionary
 empty