

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of streptococcus mutans adhesion on stainless steel orthodontic wire coated with titanium oxide in orthodontic patients

Protocol summary

Study aim

The purpose of this study was to investigate the effect of stainless steel wire coating with titanium oxide on Streptococcus mutans adhesion in patients undergoing orthodontic treatment.

Design

Clinical trial with control group, with parallel group, double-blind, block randomization with a sample size of 68 persons (4 groups of 17 persons)

Settings and conduct

This clinical trial will be done in Orthodontic department of Hamadan University on 68 patients. In this study one arch is case and the opposite arch is considered as control group. Stainless steel arch wires coated with Titanium oxide are used in the case groups and conventional Stainless steel arch wires are placed in control groups. Double blinding for patients and postoperative care is done.

Participants/Inclusion and exclusion criteria

This study will be done in Orthodontic department of Hamadan University of Medical Sciences. Inclusion criteria are: 1) age range between 12 to 25 years old 2) don't use antibiotic and oral mouth wash during orthodontic treatment 3) no history of systemic disease 4) no smoking 5) don't use intra arch elastic, chain , O-ring and open coil during treatment . exclusion criteria are: 1) missing, orofacial syndroms and craniofacial anomalies 2) pregnant women 3) Diabetes, AIDS and immuno- suppressive drug users

Intervention groups

In this study orthodontics arch wires coated with titanium oxide are placed randomly in one of upper or lower arch and opposite arch is considered as control group. Patients are divided into 4 groups (A, B, C, D). Intervention in each group is as follows: Group A: exit of the wire from the mouth after one week, Group B: exit of the wire after two weeks, group c : exit the wire after three weeks and group D: exit the wire after four weeks.

Main outcome variables

Decreasing of cariogenic bacteria adhesion by using antiadherent characteristic of titanium oxide coating

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140215016582N3**

Registration date: **2019-07-03, 1398/04/12**

Registration timing: **prospective**

Last update: **2019-07-03, 1398/04/12**

Update count: **0**

Registration date

2019-07-03, 1398/04/12

Registrant information

Name

Vahid Mollabashi

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3835 2555

Email address

mollabashi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-22, 1398/05/31

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of streptococcus mutans adhesion on stainless steel orthodontic wire coated with titanium oxide in orthodontic patients

Public title
Effect of titanium oxide coating on streptococcus mutans adhesion

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients referring to Hamadan Dental School Age ranged 12-25 years old Non-use of antibacterial mouthwashes and antibiotics during treatment Non-use of interarch elastics, chain, O-ring and open coil during treatment
Exclusion criteria:
 The presence of systemic diseases such as : diabetes, AIDS and consumers of immunosuppressive drugs Pregnancy Smoking The presence of dental missing, syndroms and craniofacial anomalies

Age
From **12 years** old to **25 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
 Target sample size: **68**
 More than 1 sample in each individual
 Number of samples in each individual: **2**
 Orthodontic arch wires in upper and lower arch

Randomization (investigator's opinion)
Randomized

Randomization description
 In this study, a block randomization method is used. Group name (A, B, C, D) is written on the 4 cards and the first patient chooses one of them. The next patient chooses one of the three remaining cards, the next patient will be assigned one of the two cards and the last card allocated to the fourth patient.

Blinding (investigator's opinion)
Double blinded

Blinding description
 Participants are unaware of wires (coated or non-coated) located in the upper or lower jaw, and also, the person who evaluates the outcome is blinded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmide Ave., Hamadan university of Medical science

City

Hamadan

Province

Hamadan

Postal code

65178-38677

Approval date

2019-01-26, 1397/11/06

Ethics committee reference number

IR.UMSHA.REC.1397.791

Health conditions studied

1

Description of health condition studied

Streptococcus mutans adhesion to orthodontic wire

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Streptococcus mutans adhesion to orthodontic wires

Timepoint

Bacterial counting in 4 groups with 1 to 4 weeks interval

Method of measurement

Colony count

Secondary outcomes

1

Description

Evaluation of anti-adherent property of coated wire during the time

Timepoint

After 1 week, 2 weeks, 3 weeks, 4 weeks

Method of measurement

Colony count

Intervention groups

1

Description

Intervention group : In Group A, the orthodontic wires 0.018 stainless steel coated with 100 nm titanium oxide layer are randomly located in the upper or lower jaw and after one week exit from mouth.

Category

Prevention

2

Description

Intervention group: In Group B, the orthodontic wires 0.018 stainless steel coated with 100 nm titanium oxide layer are randomly located in the upper or lower jaw and after two weeks exit from mouth.

Category

Prevention

3

Description

Intervention group: In group C, the orthodontic wires 0.018 stainless steel coated with 100 nm titanium oxide layer are randomly placed in the upper or lower jaw and exit after three weeks from mouth.

Category

Prevention

4

Description

Intervention group: In Group D, the orthodontic wires 0.018 stainless steel coated with 100 nm titanium oxide layer are randomly placed in the upper or lower jaw and exit after four weeks from mouth.

Category

Prevention

5

Description

Control group: The control group is uncoated orthodontic wires 0.018 stainless steel that is placed in the opposite jaw in front of the intervention group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan dental school

Full name of responsible person

Vahid Mollabashi

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Shahid Fahmideh Ave., Hamadan University of Medical Science

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Email

zbanisafar@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Hamedan University of Medical Science

Full name of responsible person

Dr Saeed Bashirian

Street address

Shahid Fahmideh Ave., Hamadan University of Medical science

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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

Vice Chancellor for Research and Technology, Hamedan University of Medical Science

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

Hamedan University of Medical Sciences

Full name of responsible person

Ziba Banisafar

Position

post graduate student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Ziba Banisafar

Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Position

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Individual data including demographic characteristics and original outcome information are shared.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutes and dental material industry

Under which criteria data/document could be used

Unidentifiable information will not be provided due to the type of consent given to patients and the obligation of the investigator to comply with ethical requirements.

From where data/document is obtainable

Ziba Banisafar, Corresponding author, zbanisafar@yahoo.com Vahid Mollabashi, First author, mollabashi@umsha.ac.ir

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

After 6 month of result publication through electronic E-Mail of corresponding author and complete introduction and mention the goal from having the documentation, related file is available to the applicant.

Comments