Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of streptococcus mutans adhesion on stainless steel orthodontic wire caoted with titanuim 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 bacteries adhesion by using antiadhrent 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 caoted with titanuim oxide in orthodontic patients

Public title

Effect of titanuim 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

Aftar 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
Street address
Shahid Fahmideh Ave., Hamadan University of Medical Science
City
Hamadan
Province
Hamadan
Postal code
65178-38677
Phone
+98 81 3838 1059
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
City
Hamadan
Province
Hamadan
Postal code
6517838677
Phone
+98 81 3838 1059
Email
zbanisafar@yahoo.com
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
Street address
Shahid Fahmideh Ave.,Hamadan University of Medical Science
City
Hamadan
Province
Hamadan
Postal code
65178-38677
Phone
+98 81 3838 1059
Email
zbanisafar@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Ziba Banisafar
Position
postgraduate student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
Shahid Fahmideh Ave., Hamadan University of Medical Science
City
Hamadan
Province
Hamadan
Postal code
65178-38677
Phone
+98 81 3838 1059
Email
zbanisafar@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Ziba Banisafar
Position
Postgraduate student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
Shahid Fahmideh Ave., Hamadan University of Medical Science
City
Hamadan
Province
Hamadan
Postal code
65178-38677
Phone
+98 81 3838 1059
Email
zbanisafar@yahoo.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
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