

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

The Effect of the Titanium nitride coating on bacterial adhesion on orthodontic stainless steel wires: invivo study

Protocol summary

Summary

1)The aim of this study is evaluating the effect of titanium nitride coating on the extent of bacterial adhesion to the orthodontic stainless steel arch wires. 2)Design of the study is split mouth. 3)Setting and conduct: 20 patients (age 15-25) undergoing fixed orthodontic treatment at Islamic Azad University of Medical Sciences Dental School (year 94-95) will be selected. 4) inclusion criteria is that patients have the indication for placement of 19*25 SS archwires in both jaws. Exclusion criteria is consumption of antibiotics and antibacterial mouthwashes during this experiment. 5) each patient will serve as their own control, the coated archwire will randomly be assigned to one jaw and the opposing jaw will receive a non-coated archwire. after 4 weeks, the archwires will be removed and cut at the same lengths, the samples will be placed in sterile dishes containing saline phosphate buffer and sent to the laboratory. 6) bacterial colonies will be counted after culturing on blood agar plates.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021431250N2**

Registration date: **2017-03-07, 1395/12/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-07, 1395/12/17

Registrant information

Name

Fariborz Amini

Name of organization / entity

Islamic Azad University Of Medical Science Dental School

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Islamic Azad University Of Medical Science Dental School

Expected recruitment start date

2016-01-02, 1394/10/12

Expected recruitment end date

2017-02-28, 1395/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of the Titanium nitride coating on bacterial adhesion on orthodontic stainless steel wires: invivo study

Public title

The Effect of the Titanium nitride coating on bacterial adhesion on orthodontic stainless steel wires

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: patients which indication for placement of 19*25 Stainless steel archwires in both jaws exclusion criteria: consumption of antibiotics and antibacterial mouthwashes

Age

From **15 years** old to **25 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

-

Secondary trial Id

-

Registration date

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Islamic Azad University of Medical Science Dental School

Street address

No 4 , 10th Neyestan, Pasdaran St, Tehran

City

Tehran

Postal code**Approval date**

2016-08-20, 1395/05/30

Ethics committee reference number

IR.IAU.DENTAL.REC.1395,5

Health conditions studied**1****Description of health condition studied**

Bacterial adhesion on TiN coated orthodontic stainless steel wire

ICD-10 code

-

ICD-10 code description

-

Primary outcomes**1****Description**

Amount of Bacterial colonies

Timepoint

4 weeks after placement wires

Method of measurement

Colony count

Secondary outcomes

empty

Intervention groups**1****Description**

19*25 Stainless steel archwires will be evaluated, each patients will be their own control, the coated archwire will be assigned to one jaw randomly. After 4 weeks, the archwires will be removed and cut at similar lengths of 20 mm. they will be placed in sterile dishes containing saline phosphate buffer and sent to the lab for bacterial colony counting that includes dilution and culture on blood agar plates and eventually counting the colonies. each sample will be counted 3 times and the average number will be recorded.

Category

Other

2**Description**

The opposing jaw as a control group will be receive a non-coated 19*25 Stainless steel archwire. After 4 weeks, the archwires will be removed and cut at similar lengths of 20 mm. they will be placed in sterile dishes containing saline phosphate buffer and sent to the lab for bacterial colony counting that includes dilution and culture on blood agar plates and eventually counting the colonies. each sample will be counted 3 times and the average number will be recorded.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Islamic Azad University of Medical Science Dental School

Full name of responsible person

Dr Fariborz Amini

Street address

No 4 , 10th Neyestan, Pasdaran St, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Islamic Azad University of Medical Science Dental School

Full name of responsible person

Dr Arash Azizi

Street address

No 4 , 10th Neyestan, Pasdaran St, Tehran

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Tehran

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, Islamic Azad University of Medical Science Dental School

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**

Islamic Azad University of Medical Science Dental School

Full name of responsible person

Dr Fariborz Amini

Position

Professor

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Person responsible for updating data

Contact**Name of organization / entity**

Islamic Azad University of Medical Science Dental School

Full name of responsible person

Dr Bita Kiaee

Position

Resident of Orthodontics

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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