

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

comparison of the effect of NiTi , copper NiTi and epoxy coated NiTi wires on salivary nickel changes in orthodontic patients with metal injection molding brackets

Protocol summary

Summary

However nickel is known as an allergic and cytotoxic metal and despite the importance of nickel release from orthodontic appliances, there are no in vivo and very few in vitro studies on this issue in the case of orthodontic wires. The aim of this study is to compare the effect of three types of orthodontic wires on salivary nickel contents. This research has planned randomly, single blind and without placebo and will done by an orthodontist. This study contains three groups and who will know wire allocations in each group is only the orthodontist. The patients will be blind of wire allocations. For this purpose, saliva samples will all be coded, and patients won't be informed of their wire type. Samples contain of 42 orthodontic patients which will randomly divide to three groups, saliva samples collect in two stages, first stage is before bonding brackets and wire engagement and the second stage will be two months later. Bracket and wire type which allocate in every group are as follows: 1- Metal Injection Molding(MIM) bracket + Nickel-Titanium(NiTi) wire. 2- MIM bracket + Copper NiTi wire. 3- MIM bracket + Epoxy coated NiTi wire. Inclusion criteria are as follows: All of the patients should need fixed orthodontic treatment; They should not have intra oral crown and amalgam restoration; Should not smoke, drink alcohol and use special drugs; Should not have systemic disease and special diet; They should be inclined to long term cooperation. And exclusion criteria are as follow: Disinclination to continue cooperation; Have done any intra oral metal restoration; Have used alcohol or cigarette. Main intervention in this study is wire type such as Ni-Ti, Ni-Ti-Cu and Epoxy coated Ni-Ti and the primary outcome is nickel releasing which will be measured using atomic absorption spectrometry.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120725408N1**
Registration date: **2016-02-03, 1394/11/14**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-02-03, 1394/11/14

Registrant information

Name

Ozra Niknam

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effect of NiTi , copper NiTi and epoxy coated NiTi wires on salivary nickel changes in orthodontic patients with metal injection molding brackets

Public title

comparison of the effect of three types of orthodontic wires on salivary nickel changes in orthodontic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All of the patients should needed fixed orthodontic treatment; They should not have intra oral crown and amalgam restoration; Should not smoke, drink alcohol and use special drug; Should not have systemic disease and special dietry; They should be inclined to long term cooperation. Exclusion criteria: Disinclination to continue cooperation; Have done any intra oral metal restoration; Have used alcohol or cigarette.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, No 101, Mehr Alley, Esfand St, Golestan Ave, Ahvaz.

City

Ahvaz

Postal code**Approval date**

2015-11-21, 1394/08/30

Ethics committee reference number

IR.AJUMS.REC.1394.455

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

Malocclusion

ICD-10 code

k07.4

ICD-10 code description

malocclusion,unspecified

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

Nickel ion releasing

Timepoint

Before intervention ; 2 months after intervention

Method of measurement

Measure: Microgram/Milliliter by atomic absorption spectrometry machine

Secondary outcomes

empty

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

Control group: Metal injection molding(MIM) bracket + nickel-titanium (NiTi) wire

Category

Other

2**Description**

Intervention group: Metal injection molding(MIM) bracket + Copper nickel-titanium wire

Category

Other

3**Description**

Intervention group: Metal injection molding(MIM) bracket + Epoxy coated nickel titanium wire

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Orthodontics, Faculty of Dentistry,
Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Ozra Niknam

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City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person

Dr Nader Saki

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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, Ahvaz Jundishapur
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

Jundishapur University of Medical Sciences, Faculty of
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Full name of responsible person

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Position

Resident of Orthodontics

Other areas of specialty/work

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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