

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3320 5168

##### Email address

niknam.o@ajums.ac.ir

##### 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

#### Street address

Department of Orthodontics, Faculty of Dentistry,  
Ahvaz Jundishapur University of Medical Sciences, No  
101, Mehr Alley, Day St, Golestan Ave, Ahvaz.

#### City

Ahvaz

## 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

#### Street address

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

#### City

Ahvaz

#### 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  
Dentistry

#### Full name of responsible person

Ozra Niknam

#### Position

Resident of Orthodontics

#### Other areas of specialty/work

### Street address

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### Contact

#### Name of organization / entity

Faculty of Dentistry, Ahvaz Jundishapur University of  
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Dr Mashallah Khanemasjedi

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Associate Professor of Orthodontics

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**Web page address**

## **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*