

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Effects of fixed orthodontic treatment using casting versus metal injection molding (MIM) brackets on hair nickel and chromium levels

Protocol summary

Summary

Corrosion of orthodontic alloys may release nickel and chromium ions, resulting in contact allergy, asthma, or hypersensitivity. The effect of orthodontic treatment on systemic levels of chromium and nickel is disputed, demonstrating lack of changes or increases. Except for one recent study, all previous researches are performed on casting brackets, results of which are not necessarily generalizable to novel orthodontic technologies, MIM brackets, which may corrode in other ways. Metal injection molding (MIM) brackets have been designed to eliminate intra-bracket galvanic corrosion through one-piece design, uniform elemental distribution and lack of soldering between the bracket parts. The aim of this study is evaluating the hair concentration of nickel and chromium in hair specimens obtained from 46 orthodontic patients in two groups of casting brackets (AISI 316L, Stratus, Fairfield Orthodontic, United States) and MIM brackets (AISI 316L, Gem Petit, Fairfield Orthodontic). This measurement will be performed in two travels, immediately before treatment, and 6 months after starting of fixed orthodontic treatment. The inclusion criteria are: having indication of fixed orthodontic treatment, lack of any systemic disease and absence of any hair color or hairdressing. The patients will be divided into two groups of casting (control) and MIM (experimental) brackets (n = 23 in each group). The randomization will be done by an orthodontist, based on a random number table. The orthodontist is the only person who knows allocation. The laboratory expert and the patients will be blinded about bracket allocation. The hair specimens will be sent to Chemical Analysis Laboratory for atomic absorption spectrophotometry.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120625379N1**

Registration date: **2016-01-29, 1394/11/09**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-01-29, 1394/11/09

Registrant information

Name

Nima Haghighatjahromi

Name of organization / entity

Ahvaz Jondishapour medical science university,
Dentistry college

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Recruitment status

Recruitment complete

Funding source

Research deputy of Ahvaz Jondishapour medical science university

Expected recruitment start date

2016-01-30, 1394/11/10

Expected recruitment end date

2016-03-30, 1395/01/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of fixed orthodontic treatment using casting versus metal injection molding (MIM) brackets on hair

nickel and chromium levels

Public title

Effect of two kinds of orthodontic brackets on nickel and chromium ions levels in hair sample of patients

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion and exclusion criteria: Subjects' willingness to participate, having indication of fixed orthodontic treatment, having all permanent teeth fully erupted (no semi-eruptions, no missing or extraction) excluding third molars, lack of any systemic diseases, history of allergic reactions, smoking or alcohol consumption, absence of any caries, lack of any metal restorations (e.g., amalgam fillings or fixed prostheses) before or during treatment, having adequate length scalp hair, and absence of any hair color or hairdressing.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Jondishapour medical science university

Street address

Jondishapour medical science university, No 1, Mehr Alley, Day St, Golestan Ave, Ahvaz

City

Ahvaz

Postal code

Approval date

2015-11-21, 1394/08/30

Ethics committee reference number

IR.AJUMS.REC.1394.516

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

release of nickel ion

Timepoint

before intervention-6 months after intervention

Method of measurement

measure:microgram/gram dry hair mass- high resolution continuum source(AAS Contra AA700, Analytik Jena, Germany)

2

Description

release of chromium ion

Timepoint

before intervention-6 months after intervention

Method of measurement

microgram/gram dry hair mass- high resolution continuum source (AAS Contra AA700, Analytik Jena, Germany)

Secondary outcomes

empty

Intervention groups

1

Description

control group:bonding of stainless steel casting bracket (Fairfield Orthodontic, United States) 0.022 inch slot on upper and lower teeth

Category

Other

2

Description

intervention group: Bonding of stainless steel metal injection molding bracket (Fairfield Orthodontic, United States) 0.022 inch slot on upper and lower teeth

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthodontic department of dentistry college

Full name of responsible person

Nima Haghighatjahromi

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Dentistry college, Jondishapour medical science university, No 1, Mehr Alley, Day St, Golestan Ave, Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Jondishapour medical science

Full name of responsible person

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

Research deputy of Jondishapour medical science

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**

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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