Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 releases nickel and chromium ions, resulting 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 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 way. 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 in 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

Country

Iran (Islamic Republic of)

Phone

+98 61 3338 1005

Email address

haghighatj.n@ajums.ac.ir

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

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

City
Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research deputy of Jondishapour medical science

Full name of responsible person
Nader Saki

Street address
Research deputy, Jondishapour medical science university, No 1, Mehr Alley, Day 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
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
Jondishapour medical science university

Full name of responsible person
Nima Haghighatjahromi

Position
Resident of orthodontics

Other areas of specialty/work

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

City
Ahvaz

Postal code

Phone
+98 61 3338 1005

Fax

Email
haghighatnimaa@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Jondishapour medical science university, dentistry college

Full name of responsible person
Mashallah Khanemasjedi

Position
Associate professor of orthodontics

Other areas of specialty/work

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

City
Ahvaz

Postal code

Phone
+98 61 3336 7543

Fax

Email
masjedi kh@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz Jondishapour medical science university, Dentistry college

Full name of responsible person
Nima Haghighatjahromi

Position
Resident of orthodontics

Other areas of specialty/work

Street address
Dentistry college, Jondishapour medical science university, No 1, Mehr Alley, Day street, Golestan Ave, Ahvaz

City
Ahvaz

Postal code

Phone
+98 61 3338 1005

Fax

Email
haghighatj.n@ajums.ac.ir
haghighatnimaa@yahoo.com

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