

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

An investigation on the amount of salivary nickel and chromium in patients with fixed orthodontic appliances

Protocol summary

Summary

The purpose of this single arm study is to determine levels nickel and chromium in saliva in patients with fixed orthodontic appliances. This study included 32 orthodontic patients treated with fixed orthodontic appliances. The intervention under study is different orthodontic wires (first to third months: Niti wire from forth months: Stainless steel wire). Saliva samples are collected before the interventions and 1, 3, and 6 months after insertion of appliances. The samples will be kept at -20 degree until they will be processed. The spectrophotometric determination will be carried out using an electrothermal atomic absorbtion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011132481N2**

Registration date: **2010-12-18, 1389/09/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-12-18, 1389/09/27

Registrant information

Name

Soghra Yassaei

Name of organization / entity

Dental School

Country

Iran (Islamic Republic of)

Phone

+98 35 1823 8087

Email address

syassaei@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Assistance of Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2010-11-22, 1389/09/01

Expected recruitment end date

2010-12-22, 1389/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An investigation on the amount of salivary nickel and chromium in patients with fixed orthodontic appliances

Public title

An investigation on the amount of salivary nickel and chromium in patients with fixed orthodontic appliances

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: having permanent dentition, not having any amalgam and metal restoration, having 22 Roth brackets and bands on the teeth, having any palatal or lingual appliances welded to bands, having extraoral appliance (i.e., head gear) Exclusion criteria: unwilling to continue in the study

Age

From **12 years** old to **24 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 32

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research, Shahid Sadoughi
University of Medical Sciences, Yazd

Street address

Shahid Sadoughi University of Medical Sciences, Yazd

City

Yazd

Postal code

Approval date

2009-11-07, 1388/08/16

Ethics committee reference number

77391/1/17/پ

Health conditions studied

1

Description of health condition studied

Dental malocclusion

ICD-10 code

K07

ICD-10 code description

Dentofacial anomalies

Primary outcomes

1

Description

salivary nickel and chromium

Timepoint

Pre intervention, 1, 3, 6 months after intervention

Method of measurement

salivary of patients

Secondary outcomes

empty

Intervention groups

1

Description

Different orthodontic wires, first to third months: Niti wire
from fourth months: Stainless steel wire

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Private orthodontic clinic

Full name of responsible person

Street address

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr Soghra Yassaei

Street address

Department of Orthodontic, Faculty of Dentistry,
Dahaye Fajr Blvd, Yazd

City

Yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Sadoughi 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

Faculty of Dentistry

Full name of responsible person

Soghra Yassaei

Position

Associate Professor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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