Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of dental pulp responsiveness to electric pulp test to 0.014 and 0.012 initial arch-wire NiTi in patients under fixed orthodontic treatment: a randomized clinical trial

Protocol summary

Summary

Objectives: To evaluate dental pulp responsiveness to electric pulp Test to 0.014 and 0.012 initial arch-wire NiTi in patients under fixed orthodontic treatment. Design: A randomized clinical trial. Setting and conduct: The eligible patients under fixed orthodontic treatment who will refer to School of Dentistry during the study period will be enrolled into the trial. Inclusion criteria: Need to fixed orthodontic treatment; presence of 5 to 9 millimeters space in the anterior portion of arc; age of 10 to 60 years. Exclusion criteria: Systemic diseases; using drugs; healthy periodontal tissues; closed apex; healthy teeth; a history of orthodontic treatment. Intervention group 1: Treatment with 0.014 initial arch-wire NiTi. Intervention group 2: Treatment with 0.012 initial arch-wire NiTi. Control group: Patients who do need orthodontic treatment. Primary outcome: Assessing responsiveness to electric pulp test using EPT before intervention, 5 minutes after intervention and one month later. Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705279014N165**
Registration date: **2017-06-01, 1396/03/11**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-06-01, 1396/03/11

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-06-03, 1396/03/13

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of dental pulp responsiveness to electric pulp test to 0.014 and 0.012 initial arch-wire NiTi in patients under fixed orthodontic treatment: a randomized clinical trial

Public title

Evaluation of dental pulp responsiveness to electric pulp test to 0.014 and 0.012 initial arch-wire NiTi in patients under fixed orthodontic treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Need to fixed orthodontic treatment; presence of 5 to 9 millimeters space in the anterior portion of arc; age of 10 to 60 years. Exclusion criteria: Systemic diseases; using drugs; healthy periodontal tissues; closed apex; healthy teeth; a history of orthodontic treatment.

Age

From **10 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **510**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2017-05-13, 1396/02/23

Ethics committee reference number

IR.UMSHA.REC.1396.132

Health conditions studied

1

Description of health condition studied

Orthodontic treatment

ICD-10 code

Z46.4

ICD-10 code description

Fitting and adjustment of orthodontic device

Primary outcomes

1

Description

Assessing responsiveness to electric pulp test

Timepoint

before intervention, 5 minutes after intervention and one month later

Method of measurement

using EPT

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Treatment with 0.014 initial arch-wire NiTi.

Category

Treatment - Devices

2

Description

Intervention group 2: Treatment with 0.012 initial arch-wire NiTi.

Category

Treatment - Devices

3

Description

Control group: Patients who do need orthodontic treatment.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry

Full name of responsible person

Dr Nazanin Shahsavand

Street address

School of Dentistry, Hamadan University of Medical

Sciences, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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 and Technology, Hamadan 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

School of Dentistry

Full name of responsible person

Dr Nazanin Shahsavand

Position

Resident of Endodontics

Other areas of specialty/work

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Person responsible for updating data

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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*