

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Clinical comparison of two Initial arch wires (A.NiTi and Cu.NiTi) for amount of tooth alignment and perception of pain: A Randomized Clinical Trial

Protocol summary

Study aim

Identifying the most efficient arch wire in terms of speed correction of crowding and pain

Design

This study was a randomized, 2-arm, parallel, double blinded clinical trial with 88 participants.

Settings and conduct

Patients in need of fixed orthodontics treatment are randomly divided into two intervention group. The brackets and the bands of MBT 0.022 system are used. The method of the bracket positioning is similar. The wire is engaged in all teeth with elastomeric ligature. Alginate impression of lower arch is taken and plaster casts are made. After 6 weeks of bonding sessions, the impression is repeated again. Then on the primary and secondary casts, irregularity Index is measured for anterior segments. At the end of bonding session, the modified McGill Pain Questionnaire is given to all subjects and asked to fill it out until the next appointment. In this double blinded study, patients and researchers are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria are as follows: patients with permanent dentition (with the exception of the second and third molars); non-extraction treatment plan in lower arch, 12-25 years old; patients with crowding in anterior segment of lower arch; irregularity Index greater than 2 in lower arch; no expansion phase or distalisation in the lower arch in the process of the study, and no missing or spacing in lower arch. Exclusion criteria are as follows: active periodontal disease; history of previous orthodontic treatment, systemic disease influencing pain, chronic NSAID therapy; blocked teeth limiting brackets bonding on teeth or engagement of the wire, and patients with a history of dental pain, mucosal ulcers or temporomandibular disorders.

Intervention groups

Intervention group: 1-This group received A.NiTi 0.014 inch wires; 2-This group received Cu.NiTi 0.014 inch wires.

Main outcome variables

Irregularity Index; pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190705044102N1**

Registration date: **2019-09-26, 1398/07/04**

Registration timing: **prospective**

Last update: **2019-09-26, 1398/07/04**

Update count: **0**

Registration date

2019-09-26, 1398/07/04

Registrant information

Name

Fatemeh Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3727 7163

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-02, 1398/07/10

Expected recruitment end date

2019-12-01, 1398/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical comparison of two Initial arch wires (A.NiTi and Cu.NiTi) for amount of tooth alignment and perception of pain: A Randomized Clinical Trial

Public title

Clinical comparison of two Initial arch wires for amount of tooth alignment and perception of pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Non-extraction orthodontic treatment plan in lower arch
Patients with permanent dentition (with the exception of the second and third molars)
Patients aged 12-25 years
Patients with crowding in anterior segment of lower arch
Irregularity Index > 2 in lower arch
No expansion phase or distalization in the lower arch in the process of the study
No missing or spacing in lower arch.

Exclusion criteria:

Active periodontal disease
History of previous orthodontic treatment
Systemic disease influencing pain
Chronic NSAID therapy
Blocked teeth limiting brackets bonding on teeth or engagement of the wire
Patients with a history of dental pain, mucosal ulcers or temporomandibular disorders.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of the randomization was stratified by age (12- 17.99 and 18-25 years) and sex, with permuted blocks (fixed block size of 8). Allocation was concealed with numbered, sealed and opaque envelopes containing the group allocation cards.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this clinical trial, outcome assessor is blind about how patients are assigned. Participants in the study are also blind toward their own group while they are aware of similar costs and benefits of each arch wires. In other

words, the participants will be unaware of the nature of the arch wires used. Statistical analyst is unaware about the research hypothesis.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

Street address

Ethics Committee, Department of Research and Technology, Central Building, Shahid Beheshti Blvd.

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Kermanshah

Postal code

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Approval date

2019-09-01, 1398/06/10

Ethics committee reference number

IR.KUMS.REC.1398.632

Health conditions studied**1****Description of health condition studied**

Dental crowding

ICD-10 code

R00-R99

ICD-10 code description

Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified

Primary outcomes**1****Description**

Irregularity Index

Timepoint

Before intervention and 6 week after intervention.

Method of measurement

Caliper- millimeter

Secondary outcomes

1

Description

Pain

Timepoint

6 week after intervention

Method of measurement

The modified McGill Pain Questionnaire

Intervention groups

1

Description

Intervention group: Application of A.NiTi 0.014 inch wires as initial arch wire

Category

Treatment - Devices

2

Description

Control group: Application of Cu.NiTi 0.014 inch wires as initial arch wire

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah dental university

Full name of responsible person

Fatemeh Azizi

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Shariati st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

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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

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Aida Ekhtiari

Position

Under graduated student of dentistry

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available