

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Clinical Comparison of Two Initial Archwires (A.NITI and HANT) For Amount of Tooth Alignment and Perception of Pain- A Randomized Clinical Trial

Protocol summary

Summary

Clinical comparison of two Initial archwires (A.NITI and HANT) for amount of tooth alignment and perception of pain- Randomize, double blind(patients and analyzers) , without placebo, Multicenter, Phase two trials Fix orthodontics patient in Hamadan dental College and Health centers main inclusion criteria:Non-extraction treatment plan in lower arch25-12 : years old patient with crowding in anterior segment of lower arch:Irregularity index ≥ 2 in lower arch Main exclusion criteria:systemic disease influencing on pain :choronic NSAID therapy:exsisting of block out teeth limiting bonding of bracket on teeth 60 case sample size first intervention group: using of superelastic NITI(0/014) for 4 weeks secondry intervention group: using of HANT (0/016) for 4 weeks Year1395 primary outcome: difference of Irregularity index pre-treatment with after 4weeks secondry outcome:The degree of pain (based on modified McGill questionnaire (MPQ)) of patint in groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041327362N1**

Registration date: **2016-06-05, 1395/03/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-05, 1395/03/16

Registrant information

Name

Majid Mahmoodzade

Name of organization / entity

Dental college

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0262

Email address

mahmoodzadeh@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Government (School of Dentistry, Hamedan)

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-03-15, 1395/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Comparison of Two Initial Archwires (A.NITI and HANT) For Amount of Tooth Alignment and Perception of Pain- A Randomized Clinical Trial

Public title

Clinical Comparison of Two Initial Archwires For Amount of Tooth Alignment and Perception of Pain

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:The patient has a permanent full Dentition (with the exception of the second and third molars):Non-extraction treatment plan in lower arch: 25-12 years old patient with crowding in anterior segment of lower arch:Irregularity index ≥ 2 in lower arch:

no expansion phase or distalization in the lower jaw in the process of implementing the study is done :no missing or spacing in lower arch exclusion criteria:active periodontal disease:History of previous orthodontic treatment.:systemic disease influencing on pain:choronic NSAID therapy:exsisting of block out teeth limiting bonding of bracket on teeth:Patients with a history of dental pain , mucosal ulcers, TMD

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: **60**

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 Hamedan University of Medical Sciences and Health Services

Street address

Opposite the Mardom Park, Shahid Fahmide Boulevard, Pzhvhsh Crossroads

City

Hamadan

Postal code

654178-38741

Approval date

2016-04-23, 1395/02/04

Ethics committee reference number

IR.UMSHA.REC.1395.44

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

4 weeks

Method of measurement

Caliper-Milimeter

Secondary outcomes

1

Description

Pain

Timepoint

4 weeks

Method of measurement

Modified McGill Questionnaire

Intervention groups

1

Description

Intervention group: using of 0/014 NITI superelastic wire

Category

Treatment - Devices

2

Description

Intervention group: using of 0/016 HANT wire

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental College

Full name of responsible person

Dr.Fatemeh Azizi

Street address

Opposite the Mardom Park, Shahid Fahmide Boulevard, Pzhvhsh Crossroads

City

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2

Recruitment center

Name of recruitment center
Special Clinic of Dental College
Full name of responsible person
Dr.Fatemeh Azizi
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Front of Convenience stores, Palestine Square
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor Of Research, Hamadan University of
Medical Sciences
Full name of responsible person
Dr.Amirfarhang Miresmaeili
Street address
Opposite the Mardom Park, Shahid Fahmide
Boulevard, Pzhvhsh Crossroads
City
Hamadan
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Vice Chancellor Of Research, 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
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Full name of responsible person
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Position
Professional Doctorate in Dentistry
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