Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparision of tooth alignment and pain perception of different sizes of nickle-titanium archwires in the initial phase of fixed orthodontic treatment : randomized clinical trial

Protocol summary

Summary

This study is a double-blinded randomized clinical trial and will be conducted on patients attending comprehensive orthodontic treatment. 81 patients will be included in this study. The patients will be randomly allocated into 3 groups of 27 patients, each receiving a 0.012 inch superelastic NITI archwire (Highland Metals, USA), 0.014 inch superelastic NITI archwire (Highland Metals, USA), 0.016 inch superelastic NITI archwire(Highland Metals, USA) as initial archwire. After placement of brackets(0.022 inch slot, Roth system),initial archwires will be inserted in each group by elastomeric O'rings (American Orthodontics, USA). The method of O'rings insertion will be dependant on clinician's judgement. The variables of the study will be the amount of tooth alignment and pain peception after insertion of initial archwires. At the begining of study and before placement of brackets, impression will be taken and stone casts will be prepared to calculate the amount of irregularity index (Little's irregularity index) and vertical discrepency by digital caliper (at 0.01mm). At 4,8 and 12 weeks intervals, impressions will be taken again and the amount of irregularity index (Little's irregularity index) and vertical discrepency will be calculated. The amount of pain will be documented in each interval. The amount of pain will be evaluated subjectively using visual analogue scale.patients will be asked to determine pain severity by drawing a vertical line on the horizontal line of questionare and determine a number from 0 to 10. .the data will be analyzed by SPSS 21. At first, quantative statistical parameters will be calculated in each group and then mixed factorial ANOVA test will be used for comparison of pain amount in different intervals in three groups.if there will be significant difference, post hoc test will be used for comparison of different intervals. $p<0.05$ will be cosidered significant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042427577N1**
Registration date: **2017-04-12, 1396/01/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-12, 1396/01/23

Registrant information

Name

Aydin Sohrabi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3330 9214

Email address

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparision of tooth alignment and pain perception of different sizes of nickle-titanium archwires in the initial phase of fixed orthodontic treatment : randomized clinical trial

Public title
Comparision of tooth alignment and pain perception of different sizes of nickle-titanium archwires in the initial phase of fixed orthodontic treatment : randomized clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: presence of all permanant teeth except third molars; no quadhelix or other palatal expansion device present; no extraoral appliance; no deep overbite; no use of NSAIDS before study. Exclusion criteria: pervious orthodontic treatment; medical history or craniofacial abnormality; active periodontal disease; skeletal asymmetry; systemic diseases that might affect pain perception, or in therapy for pain conditions; previous incisor extraction; missing of incisors or canine; unwillingness of patient; vertical displacement of incisors more than 3 mm; tooth block out due to crowding.

Age
From **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **81**

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
Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences, Golgasht street, Azadi street

City
Tabriz

Postal code

Approval date
2017-01-01, 1395/10/12

Ethics committee reference number
IR.TBZMED.REC.1395.1039

Health conditions studied

1

Description of health condition studied
tooth alignment

ICD-10 code
z00-z99

ICD-10 code description
factors influencing health status and contact with health service

Primary outcomes

1

Description
Tooth alignment

Timepoint
4, 8, 12 weeks after arch wire substitution

Method of measurement
Caliper/ 0.01 mm

2

Description
Pain level

Timepoint
Immedietly, 4, 24 and 72 hours after

Method of measurement
Standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
After placement of brackets(0.022 inch slot, Roth system),0.012 inch nickle titanium archwires will be inserted by elastomeric O'rings (American Orthodontics, USA) in first interventional group. The method of O'rings insertion will be dependant on clinician's judgement. The variables of the study will be the amount of tooth alignment and pain peception after insertion of initial archwires. At the begining of study and before placement of brackets, impression will be taken and stone casts will be prepared to calculate the amount of irregularity index (Little's irregularity index) and vertical discrepency by digital caliper (at 0.01mm). At 4,8 and 12 weeks

intervals, impressions will be taken again and the amount of irregularity index (Little's irregularity index) and vertical discrepency will be calculated. The amount of pain will be documented in each interval. The amount of pain will be evaluated subjectively using visual analogue scale.patients will be asked to determine pain severity by drawing a vertical line on the horizontal line of questionare and determine a number from 0 to 10.

Category

Treatment - Devices

2

Description

After placement of brackets(0.022 inch slot, Roth system),0.014 inch nickle titanium archwires will be inserted by elastomeric O'rings (American Orthodontics, USA) in second interventional group. The method of O'rings insertion will be dependant on clinician's judgement. The variables of the study will be the amount of tooth alignment and pain peception after insertion of initial archwires. At the begining of study and before placement of brackets, impression will be taken and stone casts will be prepared to calculate the amount of irregularity index (Little's irregularity index) and vertical discrepency by digital caliper (at 0.01mm). At 4,8 and 12 weeks intervals, impressions will be taken again and the amount of irregularity index (Little's irregularity index) and vertical discrepency will be calculated. The amount of pain will be documented in each interval. The amount of pain will be evaluated subjectively using visual analogue scale.patients will be asked to determine pain severity by drawing a vertical line on the horizontal line of questionare and determine a number from 0 to 10.

Category

Treatment - Devices

3

Description

After placement of brackets(0.022 inch slot, Roth system),0.016 inch nickle titanium archwires will be inserted by elastomeric O'rings (American Orthodontics, USA) in third interventional group. The method of O'rings insertion will be dependant on clinician's judgement. The variables of the study will be the amount of tooth alignment and pain peception after insertion of initial archwires. At the begining of study and before placement of brackets, impression will be taken and stone casts will be prepared to calculate the amount of irregularity index (Little's irregularity index) and vertical discrepency by digital caliper (at 0.01mm). At 4,8 and 12 weeks intervals, impressions will be taken again and the amount of irregularity index (Little's irregularity index) and vertical discrepency will be calculated. The amount of pain will be documented in each interval. The amount of pain will be evaluated subjectively using visual analogue scale.patients will be asked to determine pain severity by drawing a vertical line on the horizontal line of questionare and determine a number from 0 to 10.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Private Clinic

Full name of responsible person

Dr. Aydin Sohrabi(orthodontist-associate professor)

Street address

Kaj building, Shariati intersection

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research (VCR) of Tabriz University of Medical Sciences

Full name of responsible person

Mohammadreza Rashidi

Street address

3d floor , No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

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 (VCR) of Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Aydin Sorabi

Position

Orthodontist/ associated professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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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