

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of tooth alignment and pain perception of different sizes of nickel-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 perception after insertion of initial archwires. At the beginning 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 discrepancy 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 discrepancy 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 questionnaire and determine a number from 0 to 10. the data will be analyzed by SPSS 21. At first, quantitative 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 considered 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

asohrabi@tbzmed.ac.ir

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

Comparison 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

Comparison 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 permanent 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: previous 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

Immediately, 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 discrepancy 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 discrepancy 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 questionnaire 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 discrepancy 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 discrepancy 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 questionnaire 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 discrepancy 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 discrepancy 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 questionnaire 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

Street address

Tabriz Dentistry Faculty, Golgasht street, Aazadi street

City

Tabriz

Postal code

5165687386

Phone

+98 41 3330 9214

Fax**Email**

ay_sorabi@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Aydin Sohrabi

Position

Orthodontist/ associated professor

Other areas of specialty/work**Street address**

Tabriz University of Medical Sciences

City

Tabriz

Postal code

5165687386

Phone

+98 41 3330 9214

Fax**Email**

ay_sohrabi@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Aydin Sohrabi

Position

Orthodontist/ associated professor

Other areas of specialty/work**Street address**

Tabriz Dentistry Faculty, Golgasht street, Aazadi street

City

Tabriz

Postal code

5157711111

Phone

+98 41 3330 9214

Fax**Email**

ay_sohrabi@yahoo.com

Web page address**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*