Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of the effect of expansion with traditional and clear expansion plate on inclination of upper molars; a randomized clinical trial

Protocol summary

Study aim

Comparison of the effect of the expansion with traditional and clear expansion plate on the torque of upper first molars

Design

Randomized clinical trial with two groups (A and B), each group containing 30 patients. we will use SNOSE method for allocation.

Settings and conduct

In this randomized controlled trial, the clinical effects of traditional and clear expansion plate will be compared. Sixty patients referring to the orthodontic department of the faculty of dentistry of Tabriz University of Medical Sciences and private office of the orthodontist will be selected according to the inclusion and exclusion criteria and randomly divided into two groups. Before and after six month of expansion stone models will be made and the torque of upper first molars will be measured on the models. then the before -after and inter-group comparisons will be done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: mixed dentition patients; the patients seeking treatment; signature of informed consent; upper arch constriction. Exclusion criteria: lack of patient cooperation in recall sessions; poor oral hygiene; extraction of upper first molars during treatment; fracture, crown or any kind of restoration which involves the occlusal surface of the molars.

Intervention groups

Traditional expansion plate: in these patients, traditional expansion plate will be used to treat upper arch constriction. Clear expansion plate: in these patients, clear expansion plate will be used to treat upper arch constriction.

Main outcome variables

The change in torque of posterior teeth; expansion of the upper arch

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170723035238N4**
Registration date: **2022-01-22, 1400/11/02**
Registration timing: **prospective**

Last update: **2022-01-22, 1400/11/02**
Update count: **0**

Registration date

2022-01-22, 1400/11/02

Registrant information

Name

ahmad behroozian

Name of organization / entity

tabriz university of medical sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-25, 1400/11/05

Expected recruitment end date

2022-03-01, 1400/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The comparison of the effect of expansion with traditional and clear expansion plate on inclination of upper molars; a randomized clinical trial

Public title
The effect of the clear expansion plate on the posterior teeth of the upper arch
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Mixed dentition patients The patients' tendency to attend in the study Signing the informed consent form to participate in the study Upper arch constriction
Exclusion criteria:
Poor patient cooperation in follow-up sessions Poor oral hygiene Extraction of upper first molars during the treatment Fracture, crown or any kind of restoration which involve the occlusal surface of the first molars
Age
From **5 years** old to **14 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
Numbered, sealed, opaque envelope (SNOSE); in this allocation system the researchers use mate envelopes. The number of the envelopes is equal with the number of the patients in each group. Then the envelops are gathered in the box. For each patients one envelope will be selected randomly and the group (case or control) will be selected in this way.
Blinding (investigator's opinion)
Not 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 Tabriz University of Medical Sciences
Street address
Central building of Tabriz medical university / Golgasht st. / Azadi st.
City
Tabriz
Province
East Azarbaijan
Postal code
5163916737
Approval date
2022-01-03, 1400/10/13
Ethics committee reference number
IR.TBZMED.REC.1400.980

Health conditions studied

1

Description of health condition studied
Upper arch constriction
ICD-10 code
M26.4
ICD-10 code description
Malocclusion, unspecified

Primary outcomes

1

Description
The change in the toque of upper posterior teeth
Timepoint
Before treatment and 6 months later
Method of measurement
Stone casts

2

Description
Arch expansion
Timepoint
Before treatment and 6 months later
Method of measurement
Stone casts

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: clear expansion plate. In This group we will use clear expansion plate for the patients who need arch expansion . Clear expansion plate is made from thermoplastic sheets which is routinely used for the fabrication of clear retainers. An expansion screw is embedded in the midpalatal region of the thermoplastic sheet. The patients will activate the screw twice a week . Each activation make separation between two halves of the appliance and expansion of the arch laterally. this

expansion may change the buccolingual inclination of the posterior teeth. the buccolingual inclination of the upper first molar will be measured and compared before and after treatment. The inter-group comparison will be dene as well.

Category

Treatment - Devices

2

Description

Intervention group: traditional expansion plate.In This group we will use traditional acrylic expansion plate for the patients who need arch expansion . acrylic expansion plate is made from the wire elements and acrylic framework. An expansion screw is embedded in the midpalatal region of the acrylic framework . The patients will activate the screw twice a week . Each activation make separation between two halves of the appliance and expansion of the arch laterally. this expansion may change the buccolingual inclination of the posterior teeth. the buccolingual inclination of the upper first molar will be The inter-group comparison will be dene as well.measured and compared before and after treatment.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry / Tabriz University of Medical Science

Full name of responsible person

Ahmad Behroozian

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Ahmad Behroozian

Position

Assistant professor

Latest degree
Specialist
Other areas of specialty/work
Dentistry
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The results of the study will be published in the scientific journals.
When the data will become available and for how long
2022-8-10
To whom data/document is available
Open access
Under which criteria data/document could be used
For researchers in medical sciences
From where data/document is obtainable
One can find the data in the journal which the article will be published in it.
What processes are involved for a request to access data/document
The access will be according to the policy of the journal which the article will be published in it.
Comments