

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 33379351

##### Email address

behrooziana@tbzmed.ac.ir

##### 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 envelopes 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 torque 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 done 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 done 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

**Street address**

Faculty of Dentistry/ Next to the Central building of Tabriz medical university/ Golgasht st. /Azadi st.

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**Email**

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**2****Recruitment center****Name of recruitment center**

Office Dr Ahmad Behroozian

**Full name of responsible person**

Ahmad Behroozian

**Street address**

Unit B, 3rd floor, Eskan Medical Building, Abresan

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Ahmad Behroozian

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**Email**

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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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**Latest degree**

Specialist

**Other areas of specialty/work**

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

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**Full name of responsible person**

Ahmad Behroozian

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Ahmad Behroozian

**Position**

Assistant professor

**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**