

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Comparison of a new method of placing orthodontic brackets (devices) with the standard method in terms of effects on smile beauty and dental inclinations and values

#### Protocol summary

##### Study aim

Comparison of a new method of placing orthodontic brackets (devices) with the standard method in terms of effects on smile beauty and dental inclinations and values

##### Design

Clinical trial parallel group second phase randomized trial with a blinded group, triple blind in 40 patients.

##### Settings and conduct

40 patients from faculty of dentistry of Mashhad University of Medical Sciences, with three-way blinding (the patients, assessing panel and statistical analyzer) and stratified randomization.

##### Participants/Inclusion and exclusion criteria

Patients in need of orthosurgery and cosmetic surgeries  
Receiving expansion by patients  
Patients who need to change the shape of their teeth after orthodontic treatment

##### Intervention groups

in 20 people who will be randomly placed in the intervention group; Roth 018 orthodontic brackets will be placed on the front teeth with the smile arc protection method. In such a way that the incisal edge of the wings of the canine bracket, will be placed gingival to the hypothetical line connecting the mesial and distal contacts of this tooth. The central bracket is placed 1.5 mm more gingivally than the distance from the incisal edge to the canine bracket slot. The lateral bracket will be bonded 0.75 to 1 mm more incisal than the central bracket. In the posterior teeth of patients in the intervention group, as in the control group, the center of the bracket slot will be placed on the LA point and in line with the longitudinal axis of the tooth.

##### Main outcome variables

1- amount of incisor display at smile 2- smile arc 3- Labiodental relationship of the lower lip and maxillary anterior teeth 4- Overbite measurement in millimeters 5-

Axial inclination of upper anterior teeth (U1 to SN and U1 to NA) 6- Measurement of occlusal plane angle 7- perceived smile esthetics

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220108053669N3**

Registration date: **2023-03-01, 1401/12/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-03-01, 1401/12/10**

Update count: **0**

##### Registration date

2023-03-01, 1401/12/10

##### Registrant information

##### Name

Peyman Esmaeili Fard Barzegar

##### Name of organization / entity

Lorestan University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4411 3043

##### Email address

esmaeili.pe@fv.lu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-21, 1401/11/01

##### Expected recruitment end date

2023-03-19, 1401/12/28

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of a new method of placing orthodontic brackets (devices) with the standard method in terms of effects on smile beauty and dental inclinations and values

**Public title**  
Comparison of a new method of placing orthodontic brackets (devices) with the standard method in terms of effects on smile beauty and dental inclinations and values

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Receiving comprehensive orthodontic treatment by patients  
Good oral hygiene and proper patient cooperation  
No need for tooth extraction in the treatment plan  
Absence of severe deep bite in patients  
**Exclusion criteria:**  
Patients in need of orthosurgery and cosmetic surgeries  
Receiving expansion by patients  
Patients who need to change the shape of their teeth after orthodontic treatment

**Age**  
From **11 years** old to **25 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients will be divided into two group of 20 people using four strata using stratified randomization. IOn this way, according to the two confounding variables of age and gendr, in terms of gender, male and female, and in terms of age, in two groups of less than 15 yearts, and 15 years and older, four strata will be obtained and with random allocation of the members of each stratum will be placed in one of two intervention or control groups with the help of a random number table.

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
In this study, due to the nature of the intervention, it is not possible to blind the clinician (orthodontist who places the brackets) to the method of placing the brackets. However, despite the knowledge of

participating in the study, the patients will not know the method of placing the brackets, and in general, it is not possible to distinguish the method of bracketing by pateints and non-spe3cialists. In addition, the individuals and the panel that measure and evaluate the outcomes of the study and the statistician will be blinded to the type of treatment received by the patients.

**Placebo**  
Used

**Assignment**  
Factorial

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**  
Mashhad University of Medical Sciences

**Street address**  
Daneshgah street

**City**  
Mashhad

**Province**  
Razavi Khorasan

**Postal code**  
1313199137

**Approval date**  
2022-06-26, 1401/04/05

**Ethics committee reference number**  
IR.MUMS.DENTISTRY.REC.1401.03

## Health conditions studied

### 1

#### Description of health condition studied

Orthosurgery

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

#### Description

amount of incisor display at smile

#### Timepoint

Measuring the amount of incisor display at smile 1- before starting orthodontic treatment 2- after completing orthodontic treatment

#### Method of measurement

With the help of a gauge or caliper in millimeters. Additionally, the smile line or lip line index, which indicates the visibility of the upper incisors and the raising of the upper lip during a smile, and divides patients into high, average, and low categories; will be

used. While smiling in the high type, the front teeth of the maxilla are seen with a significant amount of gum. In average type, maxillary anterior teeth along with only interdental gum and in low type, less than two thirds of maxillary anterior teeth are visible during smile.

## 2

### **Description**

smile arc

### **Timepoint**

Determining the type of smile arc at 1- before starting orthodontic treatment 2- after completing orthodontic treatment

### **Method of measurement**

The smile arc will be placed visually by the evaluator in one of three categories: consonant (harmony of the curvature of the upper front teeth with the arch of the lower lip), non-consonant (including flat and reverse) and not-available (in cases where the front of the maxilla is covered by the lower lip).

## 3

### **Description**

Labiodental relationship of the lower lip and maxillary anterior teeth

### **Timepoint**

Determining the labiodental relationship of the lower lip and maxillary anterior teeth at 1- before starting orthodontic treatment 2- after completing orthodontic treatment

### **Method of measurement**

It was identified by evaluating the distance between the superior border of the lower lip and inferior border of the maxillary anterior teeth. The relationship may be divided into lower lip "slightly touching" the lower border of maxillary anterior teeth, "not touching" the teeth or "covering" the anterior teeth.

## 4

### **Description**

Overbite measurement in millimeters

### **Timepoint**

Measuring the amount of overbite 1- before starting orthodontic treatment 2- after completing orthodontic treatment

### **Method of measurement**

with the help of a gauge or caliper in millimeters by assessor from study models

## 5

### **Description**

Axial inclination of upper anterior teeth (U1 to SN and U1 to NA)

### **Timepoint**

Measuring the axial inclination of upper anterior teeth 1- before starting orthodontic treatment 2- after completing orthodontic treatment

### **Method of measurement**

measured by Dolphin software version 11 after lateral

cephologram tracing

## 6

### **Description**

Measurement of occlusal plane angle

### **Timepoint**

Measuring the occlusal plane angle 1- before starting orthodontic treatment 2- after completing orthodontic treatment

### **Method of measurement**

measured by Dolphin software version 11 after lateral cephalogram tracing

## 7

### **Description**

perceived smile esthetics

### **Timepoint**

Measuring the perceived smile esthetics 1- after completing orthodontic treatment

### **Method of measurement**

frontal and close-up photograph of all patients' smiles at the end of the treatment will be given to a panel of 30 persons, including ten orthodontists, ten general dentists, and ten lay persons, and they will be asked to give their opinion about the beauty of the smiles of the treated patients in two treatment and intervention groups, by scoring their smile based on a visual analogue scale.

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: in 20 people who will be randomly placed in the intervention group; Roth 018 orthodontic brackets will be placed on the front teeth with the smile arc protection method. In such a way that the incisal edge of the wings of the canine bracket, will be placed gingival to the hypothetical line connecting the mesial and distal contacts of this tooth. The central bracket is placed 1.5 mm more gingivally than the distance from the incisal edge to the canine bracket slot. The lateral bracket will be bonded 0.75 to 1 mm more incisal than the central bracket. In the posterior teeth of patients in the intervention group, as in the control group, the center of the bracket slot will be placed on the LA point and in line with the longitudinal axis of the tooth.

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: in 20 patients who will be randomly placed in the control group; Roth 018 orthodontic brackets, in the front teeth will be placed in the usual

and standard way (i.e. the center of the bracket slot with a distance of 4.5, 4 and 4.5 mm from the incisal edge, respectively, for central, lateral and canine in children and with a distance of 5, 4.5 and 5 mm from the incisal edge respectively for central, lateral and canine in adults) and in posterior teeth, the center of the bracket slot will be placed on the LA point and in line with the longitudinal axis of the tooth.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Faculty of Dentistry, Mashhad University of Medical Sciences

**Full name of responsible person**

Alireza Ghasemzadeh

**Street address**

Faculty of Dentistry, in front of Mellat park, Vakil Abad boulevard, Khorasan Razavi.

**City**

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9177948959

**Phone**

+98 51 3841 1538

**Email**

GhayourM@mums.ac.ir

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Majid Ghayour Mobarhan

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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**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Alireza Ghasemzadeh

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Alireza Ghasemzadeh

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Full name of responsible person**

Alireza Ghasemzadeh

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**Faculty of Dentistry, In front of Mellat park, Vakil Abad  
Boulevard, Mashhad.**City**

Mashhad

**Province****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available