Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 distiniguish the method of bracketing by pateints and non-spe3cialists. In addiction, 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 cephalogram 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 boulvard, Khorasan Razavi.

City
Mashhad

Province
Razavi Khorasan

Postal code
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

Street address
Faculty of Dentistry, In front of Mellat park, Vakil Abad Boulvard, Mashhad.

City
Mashhad

Province
Razavi Khorasan

Postal code
۹۱۷۷۹۴۸۹۵۹

Phone
+98 51 3841 1538

Email
GhayourM@mums.ac.ir

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

Street address
Faculty of Dentistry, In front of Mellat park, Vakil Abad Boulvard, Mashhad.

City
Mashhad

Province
Razavi Khorasan

Postal code
۹۱۷۷۹۴۸۹۵۹

Phone
+98 51 3841 1538

Email
GhayourM@mums.ac.ir

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
Dentistry

Street address
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Postal code
۹۱۷۷۹۴۸۹۵۹
Phone
+98 51 3841 1538
Email
GhayourM@mums.ac.ir

Person responsible for updating data

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
Street address
Faculty of Dentistry, In front of Mellat park, Vakil Abad Boulvard, Mashhad.
City
Mashhad
Province
Razavi Khorasan
Postal code
۹۱۷۷۹۴۸۹۵۹
Phone
+98 51 3841 1538
Email
GhayourM@mums.ac.ir

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