Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparing the Efficacy of Maxillary Total Arch Distalization Using Zygomatic Mini-screw vs. Palatal Mini-screw: A Randomized Clinical Trial

Protocol summary

Study aim

Evaluation of clinical efficacy of infrazygomatic mini-screws in comparison to palatal mini-screws for maxillary total arch distalization

Design

A controlled, parallel-group, unblinded, randomized, phase 2 clinical trial on 20 patients. Sealedenvelope software was used for randomization.

Settings and conduct

This study will be conducted in the Orthodontics Department and the Special Clinic of the Faculty of Dentistry at Mashhad University of Medical Sciences. At the beginning of the study, lateral cephalograms and intraoral scans will be taken from the patients. Once a Class I molar relationship and an overjet of 2 to 3 millimeters are achieved, lateral cephalograms and intraoral scans will be taken again to evaluate the changes.

Participants/Inclusion and exclusion criteria

The study includes patients aged 14 to 25 years, presenting an overjet of 4 to 6 mm and classified with Class 2 malocclusion, for whom the treatment plan incorporates the retraction of maxillary teeth. People with systemic diseases or developmental and orthodontic problems affecting bone metabolism and treatment outcomes, as well as smokers and those with poor oral hygiene, were not included in the study.

Intervention groups

In the first group, two mini screws are positioned in the crest of the infrazygomatic area on both sides of the maxillary arch to facilitate distalization. In the second group, two palatal mini screws will be applied in the interdental region between the second premolar and the first molar, in conjunction with the palatal arch.

Main outcome variables

The changes in the arch from the occlusal and sagittal views will be determined using superimposition of pre- and post-treatment scans. Additionally, alterations in the axial inclination of the anterior teeth, occlusal plane changes, anteroposterior changes of the first molar, and its inclination variations will be assessed on cephalograms.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241008063291N1**
Registration date: **2025-04-19, 1404/01/30**
Registration timing: **prospective**

Last update: **2025-04-19, 1404/01/30**
Update count: **0**

Registration date

2025-04-19, 1404/01/30

Registrant information

Name

Peyman Zamanipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3864 9855

Email address

zamanipourp4022@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-20, 1404/02/30

Expected recruitment end date

2026-05-20, 1405/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Efficacy of Maxillary Total Arch Distalization Using Zygomatic Mini-screw vs. Palatal Mini-screw: A Randomized Clinical Trial

Public title

Comparing the Efficacy of Maxillary Total Arch Distalization Using Zygomatic Mini-screw vs. Palatal Mini-screw

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals exhibiting a mild Class 1 or Class 2 skeletal relationship with an overjet ranging from 4 to 6 mm and an A point - Nasion - B point angle (ANB) between 1 and 5 degrees Class 2 canine relationship and Class 2 half cusp molar relationship bilaterally Aged between 14 to 25 years With a crowding measurement of less than 5 mm indicating the suitability for a non-extraction treatment plan All permanent teeth fully erupted, excluding the wisdom teeth Frankfort-Mandibular plane angle (FMA) between 22 and 28 degrees

Exclusion criteria:

Systemic disease or the use of pharmacological agents influencing bone metabolism Complications such as posterior crossbite, dental anomalies, skeletal asymmetry, and syndromic conditions Improper oral hygiene Prior history of orthodontic intervention Smoker

Age

From **14 years** old to **25 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

To facilitate randomization of participants into two groups, the Sealed Envelope software will be utilized, employing combined blocks of four and two. In this type of assignment, blocks of four letters long consisting of the letters A and B are used, so that each block contains two letters A and two letters B. Also, blocks of two are used randomly. Therefore, 20 combinations of the letters A and B are generated, which are placed in a matte envelope in the order they are generated by the sealedenvelope software and its number is written on the envelope. The first person takes envelope number 1, the envelope is opened and assigned to the relevant group. Then the second person takes envelope number 2 and so on until envelope number 20.

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 Mashhad University of Medical Sciences

Street address

Vakilabad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9188354376

Approval date

2024-10-12, 1403/07/21

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1403.118

Health conditions studied

1

Description of health condition studied

Class II skeletal patients

ICD-10 code

M26.212

ICD-10 code description

Malocclusion, Angle's class II

Primary outcomes

1

Description

Maxillary first molar position measurements

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the treatment

Method of measurement

Dolphin Imaging 11.8 Premium software

2

Description

Occlusal plane angle

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the treatment

Method of measurement
Dolphin Imaging 11.8 Premium software

3

Description
Maxillary central incisor angle
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the treatment
Method of measurement
Dolphin Imaging 11.8 Premium software

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention group: In the first group, for distalization of the maxillary arch, Jeil JS 2mm×12mm mini screws (Korea, Seoul) are used, which are placed in the infrazygomatic crest on both sides of the arch, and a power arm of appropriate length is used on the archwire so that the line of force action passes through the center of resistance of the maxillary dentition. Anatomically, the infrazygomatic crest is a bony prominence of the zygomatic process that gradually fades towards the buccal region of the maxilla, and clinically, it is a bony ridge that is palpable in the curvature between the alveolar and zygomatic processes of the maxilla. To place the infrazygomatic mini-screw, first penetrate the cortical bone by 1mm perpendicular to the longitudinal axis of the adjacent teeth in the attached gingiva, and then gradually and continuously change the direction of the screw driver by 60 to 70 degrees relative to the occlusal plane and onto the frontal plane so that the mini-screw is placed in the maximum bone thickness of the buccal area of the molar teeth without damaging their roots. The force is applied by a Niti closed coil spring 150gr on each side and patients are seen at 3-week intervals. Changes are evaluated after achieving a class I molar relationship.
Category
Treatment - Devices

2

Description
Second Intervention group: In the second group, two Jeil G2 1.6mm×8mm palatal mini-screws (Korea, Seoul) will be used in the interdental area of the second premolar and first molar (one on each side) along with the palatal arch to retract the entire maxillary dental arch. The force applied by Niti closed coil spring 150gr on each side is applied to the palatal arch hooks and the patients are visited at 3-week intervals. After reaching a class I molar relationship, the changes are evaluated.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry, Mashhad University of Medical Sciences
Full name of responsible person
Peyman Zamanipour
Street address
Mashhad University of Medical Sciences, Azadi Square, Vakilabad Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Phone
+98 51 3806 7100
Email
zmppeyman@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Mashhad University of Medical Sciences, Azadi Square, Vakilabad Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Phone
+98 51 3806 7100
Email
zmppeyman@gmail.com
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
Peyman Zamanipour
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
No. 74, 24th Daneshjoo Ave., Daneshjoo Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9188354376
Phone
+98 51 3864 9855
Email
zmppeyman@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Peyman Zamanipour
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
No. 74, 24th Daneshjoo Ave., Daneshjoo Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9188354376
Phone
+98 51 3864 9855
Email
zmppeyman@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Peyman Zamanipour
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
No. 74, 24th Daneshjoo Ave., Daneshjoo Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9188354376
Phone
+98 51 3864 9855
Email
zmppeyman@gmail.com

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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available