Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of direct and indirect methods in retraction of maxillary anterior teeth by mini-screw in orthodontic patients: A randomized clinical trial.

Protocol summary

Study aim
Comparison of direct and indirect method in retraction of maxillary anterior teeth using mini screw.

Design
A randomized, double-blind, controlled clinical trial

Settings and conduct
Twenty-four patients with maxillary dentoalveolar protrusion will be randomly divided into two groups, group I (12 patients): direct en-mass retraction and group II (12 patients): indirect en-mass retraction. The treatment plan for all patients in both groups will include maxillary first premolar extraction on both sides. All levels of Oral Scan will be provided after leveling and alignment. The retraction in both groups will continue until the Cl I canonical relationship and the Insisurian relationship are achieved. The study and information gathering area of the Department of Orthodontics and Special Clinics of Mashhad School of Dentistry and private offices is located in Mashhad.

Participants/Inclusion and exclusion criteria
1- having permanent teeth 2- good oral hygiene 3- skeletal pattern of Cl I or Cl II 4- no transverse anomaly 5- no systemic disease with contraindication for orthodontic treatment and 6- no systemic or allergic disease for use Anchorage unit has skeletal contraindication, 7- staying more than 4 mm in distal canine after Alignment & Leveling 1- Poor oral health 2- Drug history 3- Systemic disease 4- Hormonal imbalance, Failed mini-screw

Intervention groups
In the intervention group, retraction of maxillary anterior teeth will be investigated using direct mini-screw. In the retraction control group, the maxillary anterior teeth will be examined indirectly using a mini-screw.

Main outcome variables
In this study, the loss of anchorage will be measured using linear and angular lateral cephalometric and oral scan measurements.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200111046078N1**
Registration date: **2020-03-22, 1399/01/03**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-22, 1399/01/03**
Update count: **0**

Registration date
2020-03-22, 1399/01/03

Registrant information

Name
Mohammad Sadegh Nazari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-05, 1398/01/16

Expected recruitment end date
2021-02-03, 1399/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of direct and indirect methods in retraction of maxillary anterior teeth by mini-screw in orthodontic patients: A randomized clinical trial.

Public title
Comparison of direct and indirect methods in retraction of maxillary anterior teeth by mini-screw in orthodontic patients: A randomized clinical trial.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
1- Having permanent teeth 2- Good oral hygine 3. Skeletal pattern of Cl I or Cl II 4- No transverse anomaly 5. No systemic disease that has contraindication for orthodontic treatment 6. Not having any systemic or allergic disease that is contraindicated for the use of the skeletal anchorage unit. 7. Remaining more than 4 mm of space in the distal canine after Alignment & Leveling.

Exclusion criteria:
1- Poor oral hygine 2- History of drug use 3. Systemic disease 4- Hormonal imbalance, Failed mini-screw.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization models such as lane or line, random number table or computer randomization methods will be used. And we will put every client in the intervention or control group, for example by dropping coins, lane , and lines.

Blinding (investigator's opinion)
Double blinded

Blinding description
Since both groups of patients are treated the same way, and the only difference between the two groups is in mechanical therapy, it is natural that patients are not aware of the type of mechanical therapy. Since the statistical data is provided to the statistical adviser without specifying the group name, it is obvious that the statistical advisor is not aware of the groups.

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., Mellat Park, Mashhad University of Medical Sciences, Faculty of Dentistry, Deputy of Research and Technology

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948959

Approval date
2019-12-29, 1398/10/08

Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1398.112

Health conditions studied

1

Description of health condition studied
Malocclusion, Angle class II

ICD-10 code
M26.212

ICD-10 code description
Malocclusion, Angle's class II

Primary outcomes

1

Description
Anchorage loss due to lateral cephalometric radiographics and oral scan

Timepoint
Lateral cephalometry at baseline (before treatment); oral scan after leveling & alignment; oral scan and lateral cephalometry after space closure.

Method of measurement
Linear and angular measurements of variables from oinal scan and lateral cephalometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group 1: direct en mass retraction: The treatment plan for all patients in both groups will include maxillary first premolar extraction on both sides. After the pre-treatment records (lateral cephalometry and cast) were taken from the patients, Roth system brackets (0.018×0.028) will be bandaged for all patients. Lateral cephalometry and Oral Scan will be provided for all patients after leveling and alignment. Then the miniscrews (8 mm 4 1.4 mm in diameter of the bracket type, Jeil ؛ Dentos, Daegu, South Korea) will be anesthetized on the buccal side of the interstitial bone in the gingiva attachment between the second premolar and the first molar. (33). The retraction in both groups will continue until the Cl I canonical relationship and the Insisurian relationship are achieved. After closure of the extraction space, all patients in both cephalometric and Oral Scan radiographs will again be taken to evaluate the variables (33 and 20). Arch wires stainless steel (0.016 02 0.02) with crimpable hooks in distal lateral incisor in maxilla, and 150 g force on each side with a nickel titanium coil spring closed from implant to crimpable hooks Expanded in parallel with occlusal planes applied for en-mass retraction of maxillary anterior teeth. En-mass retraction will be performed after 3 weeks of miniscrew placement (due to lack of rapid force loading and failure of miniscrew). Coil springs are checked for strength every 3 weeks. After the Leveling & Alignment phase, all patients will receive lateral cephalometry and Oral Scan. The retraction continues until the Cl I canonical relationship and the insisural relationship are achieved. After the closure of the extraction space, all patients will be re-taken with cephalometric radiography and Oral Scan to evaluate the variables.

Category

Treatment - Devices

2

Description

Intervention group: Intervention group 2: indirect en mass retraction: The treatment plan for all patients in both groups will include maxillary first premolar extraction on both sides. After the pre-treatment records (lateral cephalometry and cast) were taken from the patients, Roth system brackets (0.018×0.028) will be bandaged for all patients. Lateral cephalometry and Oral Scan will be provided for all patients after leveling and alignment. Then the miniscrews (8 mm 4 1.4 mm in diameter of the bracket type, Jeil ؛ Dentos, Daegu, South Korea) will be anesthetized on the buccal side of the interstitial bone in the gingiva attachment between the second premolar and the first molar. (33). The retraction in both groups will continue until the Cl I canonical relationship and the Insisurian relationship are achieved. After closure of the extraction space, all patients in both cephalometric and Oral Scan radiographs will again be taken to evaluate the variables (33 and 20). In the indirect method, the mini-screws will passively attach to the first molars using a 0.016 × 0.02 02 0.02 stainless steel auxiliary wire, which provides the indirect anchorage. En-mass retraction after 3 weeks of miniscrew placement (due to failure to load fast and failure of miniscrew) with a closed coil spring nickel titanium alloy (150 g force on each side) mounted to the hook between lateral and canine incisors Gets Started. After closure of the extraction space, cephalometric radiographs and Oral Scans will be taken from patients to evaluate variables.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Orthodontics, School of Dentistry, Mashhad University of Medical Sciences; Orthodontic

Full name of responsible person

Mohammad Sadegh Nazari

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Vakilabad Blvd., Mellat Park, Department of Orthodontics, Faculty of Dentistry,

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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

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
Mohammad Sadegh Nazari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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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
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