

# 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 CI 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 CI I or CI 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)

##### Phone

+98 66 3313 3223

##### Email address

msn.dentist@yahoo.com

##### 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 hygiene 3. Skeletal pattern of CI I or CI 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 hygiene 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 analyst

**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 adviser 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 oral 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 CI 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 CI 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 CI 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

##### Street address

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

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948959

##### Phone

+98 51 3882 9501

##### Email

msn.dentist@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr. Hosein Bagheri

##### 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

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##### Phone

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##### Email

DENTResearch@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**

Mohammad Sadegh Nazari

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

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msn.dentist@yahoo.com

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohammad Sadegh Nazari

**Position**

Resident

**Latest degree**

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**Other areas of specialty/work**

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**Person responsible for updating data****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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**Fax****Email**

msn.dentist@yahoo.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