

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Investigating the effect of alveolar bone micro-osteoperforation on the rate of orthodontic tooth movements

#### Protocol summary

##### Study aim

Investigating the effect of micro-osteoperforation on the rate of orthodontic tooth movement.

##### Design

Randomized clinical trial, split mouth, 40 patients, blinded outcome assessment and data analysis with simple Randomization and concealed randomization using sealed envelopes.

##### Settings and conduct

Study will be performed prospectively at school of dentistry, Kermanshah University of Medical Sciences. Following leveling and alignment, miniscrews will be inserted between maxillary second premolar and maxillary first molar. Upper jaws of patients will be scanned to make digital models and 5 micro-osteoperforations (3 micro-osteoperforations (MOPs) in buccal plate and 2 MOPs in palatal plate) will be made using Orthonia screwdriver (Jail) 3 mm distal to canine of intervention group. Perforations have 1.6 mm width and 3-4 mm depth. The maxillary canines of both sides of maxilla will be retracted by using Closed coil spring (150 g, 6 mm). One, two, three, four and five months after retraction, upper jaws of patients will be scanned and the models will be superimposed (Ceramill software) on baseline models to assess the amount of canine movement. Data analyzer and outcome assessor will be blind to the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Class II division I malocclusion; 16-25 years of age; Female patients  
Exclusion criteria: Craniofacial disorders; Systemic disorders; Smoking; Poor oral hygiene; High buccal frenum; Lack of adequate attached gingiva; Gingivitis

##### Intervention groups

Intervention Group: Canine retraction towards the extracted first premolar space in addition to five micro-osteoperforations in distal of canine with 3-4 mm of depth and 2mm space between them. Control Group: Canine retraction towards the extracted first premolar space.

#### Main outcome variables

The rate of canine movement 1, 2, 3, 4 and 5 months after the beginning of retraction.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190710044168N1**

Registration date: **2019-08-02, 1398/05/11**

Registration timing: **prospective**

Last update: **2019-08-02, 1398/05/11**

Update count: **0**

##### Registration date

2019-08-02, 1398/05/11

##### Registrant information

##### Name

Parzhin Moradi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3722 2400

##### Email address

parzhin.moradi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### Expected recruitment end date

2020-04-03, 1399/01/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of alveolar bone micro-osteoperforation on the rate of orthodontic tooth movements

**Public title**  
Investigating the effect of micro-osteoperforation on the rate of tooth movements

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Class II division I malocclusion 16-25 years of age Female patients  
**Exclusion criteria:**  
Craniofacial disorders Systemic disorders Smoking Poor oral hygiene High buccal frenum Lack of adequate attached gingiva Gingivitis Insufficient distance between roots

**Age**  
From **16 years** old to **25 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **40**  
More than 1 sample in each individual  
Number of samples in each individual: **2**  
Two different samples would be attributed to each person: the rate of maxillary left canine movement and the rate of maxillary right canine movement.

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

**Randomization description**  
The randomization would be accomplished by using simple randomization method. The intervention will be randomly allocated to either the right or left side with a 1:1 allocation ratio. Each patient will be asked to pick a sealed envelope which includes a letter A or B (A: right B: left) to assign the intervention to either the right or left side.

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

**Blinding description**  
Blinding of either patient or clinician is not possible. Blinding would be accomplished at the data collection stage, in which the outcome assessor is blinded to where the micro-osteoperforation will be applied. Also, statistical analysis will be performed by an expert who is blind to the intervention.

**Placebo**  
Not used

**Assignment**

Parallel

**Other design features**  
split mouth design

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

##### Street address

Ethics Committee, Vice Chancellor for Research and Technology, Building No.2, Kermanshah University of Medical Sciences, Shahid Beheshti Boulverd

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6714673159

#### Approval date

2019-06-22, 1398/04/01

#### Ethics committee reference number

IR.KUMS.REC.1398.234

## Health conditions studied

### 1

#### Description of health condition studied

Orthodontic tooth movement

#### ICD-10 code

M26.4

#### ICD-10 code description

Malocclusion, unspecified

## Primary outcomes

### 1

#### Description

Rate of canine movement

#### Timepoint

Right before retraction, 1, 2, 3, 4 and 5 months after canine retraction

#### Method of measurement

The digital models at first, second, third, fourth and fifth months will be superimposed on the baseline 3D model and the distance between the middle projection from the distal surface of canine in baseline model and the middle projection from distal surface of the models at month 1, 2, 3, 4 and 5 will be measured using Ceramill software.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Five micro-osteoperforations (3 micro-osteoperforations (MOPs) in buccal plate and 2 MOPs in palatal plate) will be made using Orthonia, Jail company with DC 2.4 v handpiece and straight type driveholder at 3 mm distal to canine. Perforations will have 1.6 mm width and 3-4 mm depth. The process will be done under local anesthesia (lidocaine with 1:100000 epinephrine 2%). Acetaminophen will be advised to control the pain. The maxillary canine will be retracted by using Closed coil spring (150 g, 6 mm) connecting the maxillary canine bracket to the miniscrews between the maxillary second premolar and first molar.

#### Category

Treatment - Other

### 2

#### Description

Control group: The maxillary canine will be retracted by using Closed coil spring (150 g, 6 mm) spring connecting the maxillary canine bracket to the miniscrews between the maxillary second premolar and first molar.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Faculty of Dentistry

##### Full name of responsible person

Dr. Amin Golshah

##### Street address

Across from the post office, above Shora st, Dr Shariati st

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6713954658

##### Phone

+98 83 3722 2400

##### Email

amin.golshah@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Farid Najafi

#### Street address

Vice Chancellor for Research and Technology,  
Building No.2, Kermanshah University of Medical  
Sciences, Shahid Beheshti Boulevard

#### City

Kermanshah

#### Province

Kermanshah

#### Postal code

6714673159

#### Phone

+98 83 3838 4185

#### Email

fnajafi@kums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

##### Full name of responsible person

Parzhin Moradi

##### Position

Dental student

##### Latest degree

A Level or less

##### Other areas of specialty/work

Dentistry

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Amin Golshah

**Position**

Faculty Member of Kermanshah University of Medical Sciences

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Parzhin Moradi

**Position**

Dental student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

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**Email**

parzhin.moradi@kums.ac.ir

**Web page address**

## 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**

Not applicable