

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 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 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

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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

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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

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Parzhin Moradi

Position

Dental student

Latest degree

A Level or less

Other areas of specialty/work

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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