

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Effect of miniscrew entrance angulation in buccal area of maxillary bone of patients applicant for orthodontic treatment on clinical success rate

#### Protocol summary

##### Study aim

Determination of effect of miniscrew entrance angulation in buccal area of maxillary bone of patients applicant for orthodontic treatment on clinical success rate

##### Design

Randomized clinical trial, 46 patients, blinded outcome assessment and data analysis with simple Randomization and concealed randomization using sealed envelopes.

##### Settings and conduct

The study, will be conducted as a randomized, clinical trial, in faculty of dentistry of Kermanshah University of Medical Sciences in 46 patients applicant for using miniscrews in their treatment plan in buccal plate of maxillary bone in order to retract maxillary canine into the area of extracted first premolar, are chosen. following the leveling and aligning, miniscrews are randomly placed in each side at 90 or 45 degree angles. Patients will be monitored for 6 months each month and symptoms of treatment failure, including redness, inflammation, unbearable pain, and unacceptable movement of miniscrew, as determined by the Periotest device, will be recorded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with Class II malocclusion who need canine retraction into the space of extracted first premolar. Exclusion criteria: patients with craniofacial syndromes, insufficient attached gingiva, smoking, systemic disorders and poor oral hygiene.

##### Intervention groups

Intervention group1: mini-screw placement on one side of patient maxillary bone in 45 angle degrees.  
Intervention group2 : mini-screw placement on one side of patient maxillary bone in 90 angle degrees.

##### Main outcome variables

success rate in miniscrew placement angulation of 45 and 90 degree angles.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190901044659N1**

Registration date: **2020-02-18, 1398/11/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-02-18, 1398/11/29**

Update count: **0**

##### Registration date

2020-02-18, 1398/11/29

##### Registrant information

##### Name

kimia gorji

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3722 2400

##### Email address

kimia.gorji@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-30, 1398/10/09

##### Expected recruitment end date

2020-03-12, 1398/12/22

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of miniscrew entrance angulation in buccal area of maxillary bone of patients applicant for orthodontic treatment on clinical success rate

#### Public title

Effect of miniscrew entrance angulation on clinical success rate

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Class II (cl II ) malocclusion Need for canine retraction into the space of extracted first premolar

##### Exclusion criteria:

Existing of Craniofacial Syndromes poor oral Hygiene Existing of systemic diseases

#### Age

No age limit

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **46**

More than 1 sample in each individual

Number of samples in each individual: **2**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The randomization would be accomplished by using simple randomization method. in the way that an envelop containing the angle and one containing the side of placement of the miniscrew will be chosen for each patient and the patient wont be aware of this choice.

#### Blinding (investigator's opinion)

Triple blinded

#### Blinding description

The patient, the outcome assesor and the statistical analyser are blinded to the miniscrew placement angle of each side.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### 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

2019-10-13, 1398/07/21

#### Ethics committee reference number

IR.KUMS.REC.1398.694

### Health conditions studied

#### 1

##### Description of health condition studied

Dental malocclusion

##### ICD-10 code

M26.4

##### ICD-10 code description

Malocclusion, unspecified

### Primary outcomes

#### 1

##### Description

Clinical success of mini-screw placement on 90 and 45 angle degrees which means lack of inflammation signs such as swelling, redness and , etc., also the absence of unbearable pain for the patient.

##### Timepoint

Each month over 6 months after applying orthodontic force.

##### Method of measurement

Using Periotest device and the visual analogue scale of pain in patient in duration of treatment.

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group1: Intervention group: the treatment will be done by roth system of Discovery brackets from Dentarome company, made in Germany, and American Orthodontist company bands. after leveling and aligning with Nickle- Titanium 0.16 wires and achieving 25\*17 stainless still wires, mini-screrws will be placed on one side of maxilla in 45 angle degrees.

##### Category

Treatment - Other

## 2

### Description

Intervention group2: the treatment will be done by roth system of Discovery brackets from Dentarome company,made in Germany, and American Orthodontist company bands.after leveling and alighning with Nickle-Titanium 0.16 wires and achieving 25\*17 stainless still wires, mini-screrws will be placed on one side of maxilla in 90 angle degrees.

### 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 Boulverd

##### City

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##### 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

Kimia Gorji

##### Position

Dental student

##### Latest degree

A Level or less

##### Other areas of specialty/work

Dentistry

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

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##### Province

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##### Email

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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

##### Street address

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

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Kimia Gorji  
**Position**  
Dental Student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Dentistry  
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**Email**  
kimia.gorji@kums.ac.ir

## 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