# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Oct 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 alighning, 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 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 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

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+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

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Kermanshah

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**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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## 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**

Kimia Gorji

**Position**

Dental Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

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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**

Not applicable