

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 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 assessor 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

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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

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
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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