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

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
Kermanshah

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Kermanshah

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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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kimia.gorji@kums.ac.ir

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