

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

A comparison of the effect of taper and cylindrical miniscrew designs on clinical success rate and pain in orthodontic patients

Protocol summary

Summary

The aim of this randomized, single blind study is to compare the success rate of cylindrical and taper miniscrews in orthodontic treatment. The samples will be selected from the patients admitted to the orthodontic department of dental faculty of Tabriz University of Medical Sciences or the private office of proposal administrator in 2016-2017. Inclusion criterion is a treatment plan of orthodontic miniscrew placement on each side of maxilla to provide absolute anchorage for anterior teeth retraction. Patients with any compromising bone disease will be excluded. According to the effect of age on success rate of miniscrews, stratified randomization will be done among patients under and over 16 years old. Patients will randomly be allocated to intervention (taper miniscrews) and control (cylindrical miniscrews) groups. 106 taper miniscrews in 53 patients of intervention group and 106 cylindrical miniscrews in 53 patients of control group (212 miniscrews in 106 patients overall) will be inserted on each side of maxilla between first molar and second premolar. Insertion torque will be measured by torque measurement device. The patient will be unaware of study groups but the clinician will be aware of miniscrew design, inevitably. The mobility as an indicator of miniscrew failure will be evaluated every 4 weeks up to 40 weeks. The amount of pain will be registered by the patient immediately after miniscrew placement and 6hours, 24hours, 48hours, and a week after in a special form. The primary outcomes are to be no significant difference in clinical success rate and/or pain between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201607049569N3**

Registration date: **2016-08-02, 1395/05/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-02, 1395/05/12

Registrant information

Name

Amir Mohammadi

Name of organization / entity

Department of Orthodontics of Dental Faculty of Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 3335 5965

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Recruitment status

Recruitment complete

Funding source

Dental Faculty, Tabriz University of Medical Sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2017-03-05, 1395/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effect of taper and cylindrical miniscrew designs on clinical success rate and pain in orthodontic patients

Public title

Effect of miniscrew design on survival rate and pain in orthodontic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: A treatment plan to insert miniscrews on both sides of maxilla between the second premolar and the first molar for retraction of anterior teeth.

Exclusion criteria: Any disease compromising bone quality like osteoporosis, osteomalasia, and osteopetrosis.

Age

From **10 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **212**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Ethics Committee of Tabriz University of Medical Sciences, Vice Chancellor for Research of Tabriz University of Medical Sciences, Tabriz University of Medical Sciences, Golgasht Street

City

Tabriz

Postal code

Approval date

2016-07-26, 1395/05/05

Ethics committee reference number

IR.TBZMED.REC.1395.417

Health conditions studied

1

Description of health condition studied

Orthodontic Anchorage Procedures

ICD-10 code

Z45.8

ICD-10 code description

Adjustment and management of other implanted devices

Primary outcomes

1

Description

mobility in miniscrews

Timepoint

every 4 weeks after miniscrew placement

Method of measurement

By placing a calibrated probe on the miniscrew and lateral movement, if mobility is greater than 0.5 millimeter, the miniscrew is designated mobile.

2

Description

pain

Timepoint

immediately after miniscrew placement and 6hours, 24hours, 48hours, and a week after

Method of measurement

registration of the amount of pain from 0 (minimum pain) to 10 (maximum pain) according to Visual Analogue Scale in special times

Secondary outcomes

1

Description

Amount of insertion torque of the miniscrews

Timepoint

during insertion of miniscrews

Method of measurement

Torque measurement device (Orthonia, JEIL Company)

Intervention groups

1

Description

Control group: 106 cylindrical miniscrews manufactured by General Implant Company, with a diameter of 1.6mm and a length of 11mm will be inserted on both sides of maxilla between second premolar and first molar in 53 patients. During insertion of miniscrew, insertion torque will be measured by torque measurement device. miniscrews will be loaded immediately.

Category

Treatment - Other

2

Description

Intervention group: 106 taper miniscrews manufactured by General Implant Company, with a diameter of 1.6mm

and a length of 11mm will be inserted on both sides of maxilla between second premolar and first molar in 53 patients. During insertion of miniscrew, insertion torque will be measured by torque measurement device. miniscrews will be loaded immediately.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

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Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research of Tabriz University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research of Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty