

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Comparison of Clinical Success Rates of Orthodontic Miniscrews with three different loading times: immediately, six and fourteen weeks after miniscrew placement in orthodontic patients

Protocol summary

Summary

The aim of this study is to evaluate success rate of orthodontic miniscrews with different loading times after their insertion. This is a randomized, not blind study. The samples will be selected from the patients admitted to the orthodontic department of dental faculty of Tabriz university of medical sciences and the office of proposal administrator in 2013-2014. Inclusion criterion is a treatment plan to insert an orthodontic miniscrew implant on each side of the maxilla between second premolar and first molar for anchorage reinforcement in anterior teeth retraction. There will be 180 sample miniscrews. In each patient, a miniscrew will be placed on each side of the maxilla between first molar and second premolar. Insertion torque will be measured by torque measurement device. According to the effect of age on success rate of miniscrews, the patients will be divided into two groups under 16 years old and older than 16 years old for assimilating of groups. Each of the patients less than 16 years old randomly will settle in one of these three loading groups: loading immediately, loading 6 weeks after miniscrew placement and loading 14 weeks after miniscrew placement. Each of the patients older than 16 years old also will settle randomly in one of these three loading groups. Because the patient and the clinician inevitably will be aware of loading time, so it will not be possible to blind this study. The mobility will be evaluated three weeks after miniscrew placement, six weeks after miniscrew placement, ten weeks after miniscrew placement and then every 4 weeks. Our primary expected outcome is to be no difference in clinical success rate (no mobility) of three groups of loading time.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201311069569N2**

Registration date: **2014-12-06, 1393/09/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-06, 1393/09/15

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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Recruitment status

Recruitment complete

Funding source

Tabriz dental faculty, Tabriz university of medical sciences

Expected recruitment start date

2013-12-01, 1392/09/10

Expected recruitment end date

2015-04-01, 1394/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of Clinical Success Rates of Orthodontic Miniscrews with three different loading times: immediately, six and fourteen weeks after miniscrew placement in orthodontic patients

Public title

The effect of different loading times on loosening of miniscrews 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 **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This site has been used for randomization and allocation: http://www.graphpad.com/quick_calcs/index.cfm . With attention to the patient age, stratified randomization will be done. Patients less than 16 years old randomly will settle in one of these three loading groups: loading immediately, loading 6 weeks after miniscrew placement and loading 14 weeks after miniscrew placement. Patients older than 16 years old also will settle randomly in one of these three loading groups. According to the previous study, 20 patients of 30 patients are older than 16 years old and 10 patients are under 16 years old.

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

2014-08-11, 1393/05/20

Ethics committee reference number

9374

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 the miniscrews

Timepoint

Three weeks after miniscrew placement, six weeks after miniscrew placement, ten weeks after miniscrew placement and then every 4 weeks

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

mobility in two groups less than 16 years old and older than 16 years old

Timepoint

Three weeks after miniscrew placement, six weeks after miniscrew placement, ten weeks after miniscrew placement and then every 4 weeks

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

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

180 miniscrews manufactured by Jeil Company, with a diameter of 1.6mm and a length of 11mm will be inserted in 90 patients. During insertion of miniscrew, insertion torque will be measured by torque measurement device. According to the age of patients, stratified randomization will be done. The patients randomly divided into 3 groups of loading time. In intervention group 1, miniscrews will be loaded after 6 weeks from miniscrew insertion.

Category

Treatment - Other

2

Description

180 miniscrews manufactured by Jeil Company, with a diameter of 1.6mm and a length of 11mm will be inserted in 90 patients. During insertion of miniscrew, insertion torque will be measured by torque measurement device. According to the age of patients, stratified randomization will be done. The patients randomly divided into 3 groups of loading time. In intervention group 2, miniscrews will be loaded after 14 weeks from miniscrew insertion.

Category

Treatment - Other

3

Description

180 miniscrews manufactured by Jeil Company, with a diameter of 1.6mm and a length of 11mm will be inserted in 90 patients. During insertion of miniscrew, insertion torque will be measured by torque measurement device. According to the age of patients, stratified randomization will be done. The patients randomly divided into 3 groups of loading time: control group and two intervention groups. In control group miniscrews will be loaded immediately.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of orthodontics of dental faculty of Tabriz university of medical sciences

Full name of responsible person

Amir Mohammadi

Street address

Department of orthodontics, Tabriz dental faculty,

Tabriz university of medical sciences, Golgasht street

City

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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

Mohammadreza Rashidi

Street address

Tabriz University of Medical Sciences, Golgasht street

City

Tabriz

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

Department of orthodontics of dental faculty of Tabriz university of medical sciences

Full name of responsible person

Amir Mohammadi

Position

Assistant professor

Other areas of specialty/work

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Full name of responsible person

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Web page address

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