Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Comparison of Clinical Success Rates of Surface Roughened Orthodontic Miniscrews with Conventional One

Protocol summary

Summary

The aim of this study is to evaluate the health care delivery system. This is a randomized, double-blind study. The samples will be selected from the patients admitted to the Orthodontic Department of Dental Faculty of Tabriz University of Medical Sciences in 2011-2012. Inclusion criterion is a treatment plan to insert an orthodontic miniscrew implant on each side of the maxilla. The exclusion criteria consist of any disease that influences bone quality such as osteoporosis, osteomalasia, osteopetrosis, and any metabolic bone disease. There will be 60 sample miniscrews. In each patient, a miniscrew placed on each side of the maxilla between first molar and second premolar. One of the miniscrews will be surface-roughened and the other one will be an ordinary one. The patients and the operator inserting the miniscrews will be blind to which side has a surface roughened miniscrew. Our primary expected outcome is to increase in clinical success rate (no mobility) of the surface-roughened orthodontic miniscrew implants in comparison with ordinary ones.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204289569N1**
Registration date: **2012-06-27, 1391/04/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-06-27, 1391/04/07

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Tabriz University of Medical Sciences

Expected recruitment start date

2012-05-09, 1391/02/20

Expected recruitment end date

2012-06-09, 1391/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of Clinical Success Rates of Surface Roughened Orthodontic Miniscrews with Conventional One

Public title

The Influence of Surface Roughening of Orthodontic Miniscrews on Their Clinical Success Rate

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

osteopetrosis, osteomalasia.

Age

From **10 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The operator inserting the miniscrews has two miniscrew boxes. Box “A” and box “B”. Only miniscrews in box “A” have been roughened. He knows that the miniscrews of one of the boxes have been roughened, but he does not know which one of the boxes has the roughened miniscrews. He just inserts the miniscrews of box “A” on the right side and the miniscrews of box “B” on the left side in the odd number patients (according to referral). Conversely, in the even number patients, he places the miniscrews of box “B” on the right side and the miniscrews of box “A” on the left side. All the patients know that the miniscrew on one of the sides is roughened, but they do not know which one of them is roughened. Therefore, the patients and the operator who inserts the miniscrews do not know which one of the inserted miniscrews is roughened; This study as aresult is a double-blind clinical trial.

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, Tabriz

City

Tabriz

Postal code

51665-118

Approval date

2012-04-05, 1391/01/17

Ethics committee reference number

308/4/6

Health conditions studied

1

Description of health condition studied

Orthodontic Anchorage Procedures

ICD-10 code

T84.9, Z45

ICD-10 code description

Unspecified complication of internal orthopaedic prosthetic device, implant and graft; Adjustment and management of other implant devices

Primary outcomes

1

Description

Detection of mobility in the miniscrews

Timepoint

Six weeks and six months after insertion of the miniscrew

Method of measurement

Check list to record the mobility

Secondary outcomes

1

Description

Amount of removal torque of the miniscrews

Timepoint

Six months after insertion of miniscrews

Method of measurement

Torque measurment device (Orthonia, JEIL Company)

Intervention groups

1

Description

Sixty miniscrews manufactured by Jeil Company, with a diameter of 1.6mm and a length of 10mm will be randomly divided into case and control groups. The case group samples will be roughened by sandblasting and acid etching. Surface roughening will be carried out as follows: First of all, the miniscrews will be polished and sandblasted with aluminum oxide particles under the pressure of 4MPa. Then irrigation will be carried out with acetone, 75% alcohol ethylic, and distilled water in an ultrasonic cleanser for 15 minutes, in turn. Subsequently the samples will be put in a solution of hydrofluoric acid with a concentration 0.11 mol per liter and nitric acid with a concentration of 0.09mol per liter at room temperature for 10 minutes. Then the samples will be maintained in an oven at 50°C for 24 hours. Subsequently the samples will be put into a solution of

hydrochloric acid with a concentration of 5.8mol per liter and sulfuric acid with a concentration of 8.96mol per liter at 80°C for 30 minutes. Finally, an oven at 50°C will be used for drying the miniscrews for 24 hours.

Category

Treatment - Devices

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

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Full name of responsible person

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Grant name

10506

Grant code / Reference number

برنامه

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