Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Evaluation of the efficiency of the new miniscrew assisted method of protracting the mandibular second molars in patients referred to the orthodontic department

Protocol summary

Study aim

Evaluation of the efficiency of the new method of bringing forward the second molar of the lower jaw with the help of mini-screw compared to the conventional method

Design

A clinical trial with a control group, with parallel groups, without blinding, stratified, on 20 patients, which is used for randomization using pass11 software.

Settings and conduct

This study will follow a randomized controlled trial design. Participants were divided into two intervention groups: mini-screw group (A) and comparison group (B). 10 participants in each group are needed to detect significant differences. The study group will include patients referred to the orthodontic department of Mashhad Dental Faculty. Participants are randomly assigned to either the miniscrew group (A) or the comparison group (B). Measurements are taken at the beginning, during the treatment and after the treatment. Descriptive statistics are used to summarize the characteristics of the participants. To analyze the data t-test are used. Blinding is not done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients who have lost their mandibular permanent first molar teeth. 2- Patients aged between 15 and 25 years Exclusion criteria: 1- Patients who will not want to continue cooperation. 2-Patients with mini-screw failure for the first time

Intervention groups

The intervention groups will include the following two groups: 1- Intervention group A, which includes patients who have lost their mandibular first molar and receive the new method. 2- Intervention group B (comparison) which includes patients who have lost their mandibular first molar and receive the conventional method.

Main outcome variables

The amount of second molar advancement per unit of time, the bone surface in the mesial side of the second molar after advancement, Changes in the angle of the second molar with the mandibular border

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230407057841N1**
Registration date: **2023-11-28, 1402/09/07**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-28, 1402/09/07**
Update count: **0**

Registration date

2023-11-28, 1402/09/07

Registrant information

Name

lohrasb dehghani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3881 4473

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-11, 1402/03/21

Expected recruitment end date

2024-10-12, 1403/07/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficiency of the new miniscrew assisted method of protracting the mandibular second molars in patients referred to the orthodontic department

Public title

Evaluation of the efficiency of the new miniscrew assisted method of protracting the mandibular second molars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Orthodontic patients who have lost their mandibular first molars and the second molars are tilted to the edentulous area and need protraction. 15-25 years old The buccolingual thickness of the bone in the edentulous area should be more than two thirds of the buccolingual thickness of the mesial root of the second molar. Absence of systemic problems affecting bone metabolism No smoking Not taking drugs affecting bone metabolism

Exclusion criteria:

Patient non-cooperation Mini screw failure once

Age

From **15 years** old to **25 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

The type of study is a clinical trial, which includes two control groups and patients. After the patients enter this study, they are randomly assigned to one of two intervention or control groups. The randomization of these patients will be simple randomization. Simple randomization is done by randomizer.org. Also, to conceal each person's chosen group, we write the relevant groups on paper and put them inside the envelope. Numbers are printed on the envelope according to the numbers generated by randomizer.org. Then people randomly pick one of the envelopes and are assigned to the group written inside the envelope.

Blinding (investigator's opinion)

Not 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 Mashhad University of Medical Sciences

Street address

no.9,bahonar Ave.,vakilabad blvd.,mashhad town

City

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Province

Razavi Khorasan

Postal code

9177944841

Approval date

2023-04-13, 1402/01/24

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1402.014

Health conditions studied

1

Description of health condition studied

mandibular first molar loss

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

mandibular second molar protraction speed

Timepoint

6 months after molar protraction

Method of measurement

Comparison of the distance of the maximum convexity of the second molar and second premolar teeth in the initial and final opg photos

Secondary outcomes

1

Description

The change of mandibular second molar angle with the mandibular border (in OPG images) before and after treatment

Timepoint

6 months after protraction

Method of measurement

OPG photos prepared

2

Description
Changes in rotation relative to the mandibular occlusion line (in study models) before and after treatment
Timepoint
6 months after protraction
Method of measurement
OPG photos prepared

3

Description
The amount of bone and its density in the mesial second molar (in CBCT images) before and after treatment
Timepoint
6 months after protraction
Method of measurement
CBCT photos prepared

Intervention groups

1

Description
Intervention group: two G2 Jeil 1.4 ∗8 miniscrews will be placed in the mesial and distal of the second premolar tooth. Then uprighting is done with the help of a rectangular loop made of 17 ∗25 mil TMA wire, which is placed in the screw slots, and after placing a T.Loop made of 17 ∗25 mil TMA wire along with a 40 degree β bend and a bend Antirotation 30 degrees teeth are brought forward
Category
Treatment - Devices

2

Description
Control group: Conventionally, after the initial alignment and placing of the steel wire 25x19, a mini screw G2 Jeil 1.4 ∗8 is placed between the 3rd and 4th teeth and connected to the 4th tooth with a ligature wire. We use Ni-Ti push coils to straighten the second molar. Then, this tooth is connected to tooth 4 with a Ni-Ti close coil spring from the buccal (bracket) and lingual (lingual button) sides with a force of 100 grams. Lingual force is applied to prevent the rotation of the second molar
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Periodontology, Faculty of Dentistry, Mashhad
Full name of responsible person
lohrasb dehghani
Street address
Vakil Abad Boulevard, corner of Park Square, Mashhad School of Dentistry, second floor
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Recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
dr.majid ghayour mobarhan
Street address
University Street - Qureshi Building - Building No. 2 - 2nd Floor
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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Dr.fahimeh farzanegan

Position
associate professor

Latest degree
Master

Other areas of specialty/work
orthodontics

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Full name of responsible person
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Position
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Latest degree
Master

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Resident

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Medical doctor

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Orthodontics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
there is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available