

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A clinical trial to compare the effect of the miniscrew-supported technique with conventional techniques in mandibular second molar uprighting in patients under orthodontic treatment

Protocol summary

Study aim

The comparison of the effect of the miniscrew-supported technique with conventional techniques in mandibular second molar uprighting in patients under orthodontic treatment

Design

Clinical trial with control group, single-blind with parallel groups, randomized on 10 patients. Table of random numbers are used for randomization.

Settings and conduct

The patients are selected from those who refer to the Dental Clinic of Mashhad, Faculty of Dentistry, Mashhad, Iran. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. The intervention group will receive the miniscrew-supported approach, and the control group will receive the conventional Melsen method for the uprighting of mandibular second molars. The person responsible for data collection is blind to the group allocation and the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patients who have already lost their first molars, those who are candidates for prosthetic treatment of the edentulous site, along with cases whose second molars are inclined at least 30 degrees. Exclusion criteria: Those with poor oral hygiene, history of using medications, systemic diseases, hormonal imbalance, and furcation involvement will be excluded from the study.

Intervention groups

Intervention group will receive miniscrew-supported appliances for uprighting of mandibular second molars. Control group will receive conventional Melsen method for uprighting of mandibular second molars.

Main outcome variables

The time required for uprighting, speed of uprighting, the rate of tooth extrusion and the bone formation rate in the mesial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210606051499N1**

Registration date: **2021-07-22, 1400/04/31**

Registration timing: **prospective**

Last update: **2021-07-22, 1400/04/31**

Update count: **0**

Registration date

2021-07-22, 1400/04/31

Registrant information

Name

Mostafa Entezari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3883 2300

Email address

heravif1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effect of the miniscrew-supported technique with conventional techniques in mandibular second molar uprighting in patients under orthodontic treatment

Public title

The uprighting of mandibular second molars in orthodontic patient

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The patients who have already lost their first molars
Cases whose second molars are inclined at least 30 degrees
The patients who are candidates for prosthetic treatment of the edentulous site.

Exclusion criteria:

Poor oral hygiene
History of using drug
Having systemic disease
Having hormonal imbalance
Furcation involvement

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: 10

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple randomization will be used by random number table based on SAS (statistical analysis system), software. A list of sequentially number 1 to 10 will be created. This list will assign numbers randomly by computer. Patients are randomly assigned according to the numbers of this list. To conceal, we use Allocation concealment, using non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes will be opened in order and the assigned group of the participant will be revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients who refer to the Dental Clinic of Mashhad, Faculty of Dentistry, Mashhad, Iran, are selected as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. The person responsible for data collection is blind to the group allocation and the type of treatment.

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

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Approval date

2021-05-15, 1400/02/25

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1400.032

Health conditions studied**1****Description of health condition studied**

Orthodontic

ICD-10 code

Z46.4

ICD-10 code description

Fitting and adjustment of orthodontic device

Primary outcomes**1****Description**

The time required for uprighting

Timepoint

Before and after the intervention

Method of measurement

Cone beam computed tomography, Orthopantomography and Periapical radiography images

2**Description**

Speed of uprighting

Timepoint

Before and after the intervention

Method of measurement

Cone beam computed tomography, Orthopantomography and Periapical radiography images

3

Description

The rate of tooth extrusion

Timepoint

Before and after the intervention

Method of measurement

Cone beam computed tomography, Orthopantomography and Periapical radiography images

4

Description

The bone formation rate in the mesial

Timepoint

Before and after the intervention

Method of measurement

Cone beam computed tomography, Orthopantomography and Periapical radiography images

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive miniscrew-supported approach for the uprighting of mandibular second molars. In this method, a mini-screw is placed in the distal second molar, and without the need for anterior teeth placement appliance, the molar operation is performed only with the help of the number one wire.

Category

Treatment - Devices

2

Description

Control group: The control group will receive the conventional Melsen method for the uprighting of mandibular second molars. In this method, a mini-screw is placed between the seventh and fifth teeth, and the apparatus is performed with the help of one spring, and the extraction is prevented with the help of the second wire.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Faculty of Dentistry Dental Clinic

Full name of responsible person

Mostafa Entezari

Street address

Dental Clinic of Mashhad Faculty of Dentistry,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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

Mostafa Entezari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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

Mashhad University of Medical Sciences

Full name of responsible person

Mostafa Entezari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mostafa Entezari

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The information obtained from the main outcomes of the study can be shared

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

The research data is exclusively accessible to the researchers working at universities and centers for scientific research

Under which criteria data/document could be used

The research data is exclusively accessible to the researchers working at universities and centers for scientific research

From where data/document is obtainable

Mostafa Entezari provides the data analysis to the applicants via email: mostafa.entezari91@gmail.com

What processes are involved for a request to access data/document

Applicants can send emails to him and receive a response within a week.

Comments