

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

A clinical trial to compare the effectiveness of miniscrew-supported appliances with pendulum appliance in maxillary first molar distalization in orthodontic patient

Protocol summary

Study aim

To compare the effectiveness of miniscrew-supported appliances with pendulum appliance in maxillary first molar distalization in orthodontic patient

Design

Totally, 30 patients whose undergoing orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, Mashhad, Iran. In this single-blind, controlled clinical trial, the patients are assigned into parallel groups using simple sampling methods

Settings and conduct

Patients whose undergoing orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, are chosen 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 group allocation and the type of drugs.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 14-20 years; class II malocclusion; class I and class II skeletal pattern.

Exclusion criteria: Miniscrew failure; having dental and bone lesions; having periodontal disease.

Intervention groups

The intervention group will receive miniscrew-supported appliances for maxillary first molar distalization. The Control group will receive a common pendulum appliance for maxillary first molar distalization.

Main outcome variables

Evaluation and comparison of the distance between lateral incisor distal contact to molars mesial contact, upper arch dimensions, the amount of distal molar movement, rate of tooth rotation, rate of root resorption, and rate of pain before and after the intervention in the two intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200509047357N1**

Registration date: **2020-05-18, 1399/02/29**

Registration timing: **prospective**

Last update: **2020-05-18, 1399/02/29**

Update count: **0**

Registration date

2020-05-18, 1399/02/29

Registrant information

Name

Haniye Kazemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3883 2300

Email address

kazemigh971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of miniscrew-supported appliances with pendulum appliance in maxillary first molar distalization in orthodontic patient

Public title

The maxillary first molar distalization in orthodontic patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 14-20 years Class II malocclusion Class I and class II skeletal pattern

Exclusion criteria:

Miniscrew failure Having dental and bone lesions Having periodontal disease

Age

From **14 years** old to **20 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects will be randomly assigned into two groups of 15 patients with blocks of 2 and 4 using randomization method. A noninvolved researcher will determine the random assignment sequencing in sampling using a statistical analysis system (SAS), computer software. Accordingly, the participants were given codes and assigned into the intervention and control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients whose undergoing orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, are chosen 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 group allocation and the type of drugs.

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

2019-11-13, 1398/08/22

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1398.106

Health conditions studied

1

Description of health condition studied

Orthodontic

ICD-10 code

Z46.5

ICD-10 code description

Fitting and adjustment of ileostomy and other intestinal appliances

Primary outcomes

1

Description

The distance between lateral incisor distal contact to molars mesial contact

Timepoint

Before and after the intervention

Method of measurement

Cone Beam Computed Tomography (CBCT)

2

Description

Upper arch dimensions

Timepoint

Before and after the intervention

Method of measurement

Cephalometric radiograph

3

Description

The amount of distal molar movement

Timepoint

Before and after the intervention

Method of measurement

Cone Beam Computed Tomography (CBCT)

4

Description

Rate of tooth rotation

Timepoint

Before and after the intervention

Method of measurement

Cone Beam Computed Tomography (CBCT)

5

Description

Rate of root resorption

Timepoint

Before and after the intervention

Method of measurement

Cone Beam Computed Tomography (CBCT)

Secondary outcomes

1

Description

Rate of pain

Timepoint

Before and after the intervention

Method of measurement

A Visual Analogue Scale (VAS)

Intervention groups

1

Description

Intervention group: Intervention group will receive miniscrew-supported appliances for maxillary first molar distalization.

Category

Treatment - Devices

2

Description

Control group: Control group will receive common pendulum appliance for maxillary first molar distalization.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Faculty of Dentistry Dental Clinic

Full name of responsible person

Haniye Kazemi

Street address

Dental Clinic of Mashhad Faculty of Dentistry,
Opposite Mellat Park, Vakilabad Blvd

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9177948959

Phone

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Email

Haniyekazemi71@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

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

Haniye Kazemi

Position

Resident

Latest degree

Medical doctor
Other areas of specialty/work
Dentistry
Street address
Dental Clinic of Mashhad Faculty of Dentistry,
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Person responsible for updating data

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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

Information on the main outcome or the like can be shared.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working at science centers and universities.

Under which criteria data/document could be used

Our data will be available for scholars working at science centers and universities.

From where data/document is obtainable

Haniye Kazemi provides the data analysis to the applicants via email: Haniyekazemi71@gmail.com

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

Applicants can respond to the email of the respondent and receive a response within a week.

Comments