

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A clinical trial to compare the effectiveness of micro-implant based appliances with pendulum appliances for maxillary molar distalization in patients requiring orthodontic treatment

Protocol summary

Study aim

To compare the effectiveness of micro-implant based appliances with pendulum appliances for maxillary molar distalization in patients who need orthodontic treatment

Design

Thirty patients whose maxillary second molars had not grown and visited Dental Clinic of Mashhad Faculty of Dentistry were randomly selected and assigned to control and intervention groups. A code was allocated to each of the participants.

Settings and conduct

Patients whose second molar had not grown and visited the Dental Clinic of Mashhad Faculty of Dentistry, Mashhad, Iran, are chosen as the participants of the study. In this single-blind study, the participants are unaware of the type of treatment

Participants/Inclusion and exclusion criteria

Study population: Age higher than 12 years; dental Class II malocclusion and skeletal malocclusion class I or II; Lack of growth maxillary second molars. Exclusion criteria: In maturity or later of CS3 stages; having certain systemic diseases.

Intervention groups

The control group undergoes treatment with pendulum appliance, a device balancing the maxillary molar teeth by using denture anchorage and palate with two active springs. The intervention group undergoes treatment with micro-implant based appliances in each side of the jaw, two mini-screws are placed in the mesial molar area

Main outcome variables

Evaluation and comparison of the difference in the maxillary first molar angular via measuring all axis dental, the amount of root recession tooth categorized into 3 Grades (G0: without resorption, G1: mild resorption, G2: moderate to severe resorption) by cephalometric radiography and the degree of pain as assessed by visual analogue scale before and 3 months

after treatment in the intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170128032230N2**

Registration date: **2018-08-08, 1397/05/17**

Registration timing: **prospective**

Last update: **2018-08-08, 1397/05/17**

Update count: **0**

Registration date

2018-08-08, 1397/05/17

Registrant information

Name

Hossein Khaki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3625 9865

Email address

khakih941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-11, 1397/09/20

Expected recruitment end date

2020-07-31, 1399/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of micro-implant based appliances with pendulum appliances for maxillary molar distalization in patients requiring orthodontic treatment

Public title

Maxillary molar distalization in patients who need orthodontic treatment

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age higher than 12 years Dental Class II malocclusion and skeletal malocclusion class I or II Lack of growth maxillary second molars

Exclusion criteria:

Having certain systemic diseases In maturity or later of CS3 stages

Age

From **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

A randomized, clinical trial based on random number table Settings and conduct

Blinding (investigator's opinion)

Single blinded

Blinding description

This single-blind study, the responsible for data collection are unaware of are unaware of 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

2016-06-29, 1395/04/09

Ethics committee reference number

IR.mums.sd.REC.1395.138

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

orthodontic

ICD-10 code

Z47.8

ICD-10 code description

Other specified orthopaedic follow-up care

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

the difference in the angle of the maxillary first molar

Timepoint

before and 3 months post-treatment

Method of measurement

cephalometric radiography

2**Description**

the amount of root recession tooth

Timepoint

before and 3 months post-treatment

Method of measurement

cephalometric radiography

Secondary outcomes**1****Description**

the degree of pain as assessed

Timepoint

before and 3 months post-treatment

Method of measurement

visual analogue scale

Intervention groups**1****Description**

Control group: Treatment with pendulum appliance, a device that distalizes the maxillary molar teeth using dental and palatal anchorage with two active springs.

Category

Treatment - Devices

2

Description

Intervention group: Treatment with mini-screw based appliances. On each side of the jaw two mini-screws in the mesial-molar area (one mini screw between the roots of the 5-6 tooth, and the other between the roots of the 4-5 teeth on the buccal surface). Then, a special spring designed for the distalization of the molar via TMA wire was tailored for each patient and mounted on mini-screws.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Faculty of Dentistry Dental Clinic

Full name of responsible person

Hossein Khaki

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3883 2300

Email

Hoseinkhaki88@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
Street

City

Mashhad

Province

Razavi Khorasan

Postal code

91375345

Phone

+98 51 3841 1538

Email

vcresearch@mums.ac.ir

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

Hossein Khaki

Position

Orthodontic Residents

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Opposite Mellat Park, Vakilabad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3883 2300

Email

Hoseinkhaki88@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hossein Khaki

Position

Orthodontic Residents

Latest degree

Specialist

Other areas of specialty/work

Dentistry
Street address
Opposite Mellat Park, Vakilabad Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Phone
+98 51 3883 2300
Email
Hoseinkhaki88@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hossein Khaki
Position
Orthodontic Residents
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Opposite Mellat Park, Vakilabad Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Phone
+98 51 3883 2300
Email
Hoseinkhaki88@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The total data to be included are the primary and secondary effects to 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 in science center and university.

Under which criteria data/document could be used

Our data will be available for scholars working in science center and university.

From where data/document is obtainable

Hossein Khaki provides the analysis code to the applicants via email: Hoseinkhaki88@gmail.com

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

Data collection was done for 10 months, data were collected one month, statistical analysis of one month, information dissemination as a article six months.

Comments