

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 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

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Opposite Mellat Park, Vakilabad Blvd

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## Person responsible for scientific inquiries

#### Contact

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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Hossein Khaki

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**Latest degree**

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**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**