Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Measuring maxillary first molars distal displacement after using a mini-screw supported appliance in class II patients in a before and after trial

Protocol summary

Summary

The aim of this study is evaluation of displacement of maxillary first molars after distalization by using skeletal anchorage system in three dimensions. The sample is consist of 30 class II patients referred to the Hamadan faculty of dentistry. They will be included in the study according to molar relationship, which should not be more than one cusp in each side. Any patient with missing teeth or large restoration or any craniofacial malformation is excluded from the study. After provision of initial diagnostic records including impression and dental casts, a dentist places two mini screws, each with 8 mm in length and 1.4 mm in diameter under local anesthesia in palatal area. He inserts them between upper second premolar and first molar with self-tapping technique, about 5-6 mm from gingival crest with an angle of 20 to 30 degrees relative to the long axis of adjacent teeth. Mini screws are loaded with an average force of 150-200 gram-force/side by using of elastic modules connected to a Trans Palatal Arch (TPA), parallel to the occlusal plane. A CBCT will be taken to evaluate the precise position of mini screws relative to adjacent teeth and direction of the force relative to molar teeth. After distal movement to desired normal position, a new impression will be taken for final evaluation. The distance from central point of maxillary rugae to mesiopalatal cusp of first maxillary molars and the distance between mesiopalatal cusp of left and right molars will be measured to evaluate displacement of maxillary molars in horizontal plane.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302269085N3**
Registration date: **2013-07-14, 1392/04/23**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-07-14, 1392/04/23

Registrant information

Name
Amirfarhang Miresmaeili
Name of organization / entity
Hamadan University of Medical Sciences
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+98 81 1823 9064
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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2013-04-12, 1392/01/23

Expected recruitment end date

2014-04-12, 1393/01/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Measuring maxillary first molars distal displacement after using a mini-screw supported appliance in class II patients in a before and after trial

Public title

Measuring backward movement of upper posterior teeth in orthodontic patients using a new distalizer appliance

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Class II molar relation, presence of both maxillary molars on both side and need for distalization in orthodontic treatment Exclusion Criteria: Any craniofacial malformation, maxillary molar root resorption and more than one cusp Class II molar relation.

Age

From **13 years** old to **35 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Hamadan University of Medical Sciences

Street address

Postcode: 65178-38677, Orthodontic Department, School of Dentistry, Shahid Fahmideh Street, Hamadan

City

Hamadan

Postal code

Approval date

2013-04-10, 1392/01/21

Ethics committee reference number

D/P/16/35/9/42

Health conditions studied

1

Description of health condition studied

Orthodontic patient with Class II molar relationship

ICD-10 code

K07.2

ICD-10 code description

Anomalies of dental arch relationship, Disto-occlusion

Primary outcomes

1

Description

Distal movement of maxillary molars (mm)

Timepoint

After completion of distalization

Method of measurement

Surface laser scanning of maxillary casts before and after trial

Secondary outcomes

1

Description

Buccal movement of maxillary first molars (mm)

Timepoint

After completion of distalization

Method of measurement

Surface laser scanning of maxillary casts before and after trial

Intervention groups

1

Description

Distal force will be applied to maxillary first molars using a palatal arch connecting right and left molars. An elastic module and ligature wire will be used for applying 150-200 gm force per side and will be changed every 3 weeks until completion of distalization.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan University of Medical Sciences

Full name of responsible person

Dr Amirfarhang Miresmaeili

Street address

Postcode: 65178-38677, Orthodontic Department, School of Dentistry, Shahid Fahmideh Street, Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research and technology, Hamadan University of Medical Sciences

Full name of responsible person

Dr. Heidar Tavilani,

Street address

Postcode: 65178-518, School of Medicine, Shahid Fahmideh Street, Hamadan

City

Hamadan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research and technology, Hamadan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Dr Amirfarhang Miresmaeili

Position

Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty