

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Cephalometric comparison of treatment with Twin Block appliance in skeletal class II div 1 patients with normal and vertical growth pattern

Protocol summary

Summary

This study is designed to compare the response to mandibular growth modification treatment in class II division I patients with vertical and normal growth pattern with Twin Block appliance for the purpose of optimal use of this appliance in the treatment. Patients should have class II molar relationship and an over jet greater than 6 mm, they should be in late mix or early permanent dentition. Patients should not use any kind of appliance for class II treatment except palatal expansion. They should not have systemic disease, craniofacial syndrome and history of orthodontic treatment. All of the patients referred to the orthodontics department of Hamadan university of medical science, who have the inclusion criteria and are volunteer for treatment will be selected. At the beginning of treatment a lateral cephalogram is taken and then the Twin Block appliance will be delivered to the patients. At least 6 months after the start of treatment and when the occlusion become stable and over jet is reduced to 1-2 millimeters, the second radiography will be taken.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014082716582N1**

Registration date: **2014-11-08, 1393/08/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-11-08, 1393/08/17

Registrant information

Name

Vahid Mollabashi

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3835 2555

Email address

mollabashi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Cephalometric comparison of treatment with Twin Block appliance in skeletal class II div 1 patients with normal and vertical growth pattern

Public title

The comparison of the effect of mandibular growth stimulator appliance in patients with different growth pattern.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: class II division I malocclusion with mandibular deficiency; class II molar relationship; overjet greater than 6 mm; in late mix or early permanent dentition. Exclusion criteria: systemic disease;

craniofacial syndrome; history of orthodontic treatment.

Age

From **9 years** old to **13 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Hamadan University of Medical Sciences

Street address

Orthodontic Department, School of Dentistry, Shahid Fahmideh Street, Hamadan

City

Hamedan

Postal code

65178-38677

Approval date

2014-05-20, 1393/02/30

Ethics committee reference number

801/9/35/16/پ

Health conditions studied

1

Description of health condition studied

malocclusion

ICD-10 code

K07.1

ICD-10 code description

Anomalies of jaw-cranial base relationship

Primary outcomes

1

Description

Reduction of overjet to 1 to 2 millimeter

Timepoint

After completion of functional therapy

Method of measurement

Cephalometric analysis with the aid of dolphin software before and after treatment

Secondary outcomes

1

Description

vertical growth control during treatment.

Timepoint

After completion of functional therapy

Method of measurement

Cephalometric analysis with the aid of dolphin software before and after treatment

Intervention groups

1

Description

patients with FMA less than 28 degrees treated with twin block appliance

Category

Treatment - Devices

2

Description

patients with FMA more than 28 degrees treated with twin block functional appliance

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan University of Medical Sciences

Full name of responsible person

Dr Vahid Mollabashi

Street address

Orthodontic Department, School of Dentistry, Shahid Fahmideh Street, Hamadan

City

Hamedan

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 Saied Bashiryan

Street address

School of Medicine, Shahid Fahmideh Street,
Hamadan 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 Vahid Mollabashi

Position

Assistant professor

Other areas of specialty/work

Street address

Orthodontic Department, School of Dentistry, Shahid
Fahmideh Street, Hamadan

City

Hamedan

Postal code

Phone

+98 81 3838 0130

Fax

Email

mollabashi@umsha.ac.ir;
vahid.mollabashi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Dr Vahid Mollabashi

Position

Assistant professor

Other areas of specialty/work

Street address

Orthodontic Department, School of Dentistry, Shahid
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Phone

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Fax

Email

mollabashi@umsha.ac.ir;
vahid.mollabashi@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

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Street address

Orthodontic Department, School of Dentistry, Shahid
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City

Hamedan

Postal code

Phone

+98 81 3838 0130

Fax

Email

vahidmolabashi@yahoo.com

Web page address

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