

# 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  
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 updating data**

**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**

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*