

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of treatment results and patient satisfaction of Classic Twin-block and Clear Twin-block in classII, div 1 malocclusions.

Protocol summary

Summary

The aim of this study is comparison of treatment results and patients satisfaction of classic twin block and clear twin block. The sample consists of 66 patients who refer to private clinic and Hamedan Faculty of dentistry with class II, div 1 malocclusion and 4 to 8 millimeter overjet. Patients with history of trauma to jaws and craniofacial syndromes are excluded from study. Initial records such as cephalometric radiograph are provided for each patient before treatment. If transverse expansion in upper dental arch is needed, expander appliance is used before functional treatment. The patients are randomly placed in two groups. In the first group, classic twin block are used. This appliance is composed of removable acrylic upper and lower plate with retentive wire components and 70 degree inclined plans. In second group, clear twin block are used. This appliance is made from clear acrylic sheets of 1.5-millimeter thickness that compress on dental casts with vacuum device. After mounting on the articulator, 70 degree inclined plans are made with acrylic. The appliances are used at least for 8 months, until reduction of overjet to 1 to 2 millimeter and reaching first molars to occlusions. After that, cephalometric radiograph are taken from patients. The implication of the study are comparison of treatment results of this two appliances with cephalometric measurements before and after treatment with the help of Dolphin software, and evaluation of patients satisfaction from orthodontic treatment 4 months after initial visits with sergel questionnaire according to Likert scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014040817180N1**

Registration date: **2014-04-30, 1393/02/10**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-04-30, 1393/02/10

Registrant information

Name

Mohammad Karim Soltani

Name of organization / entity

Hamedan Dental Faculty, Orthodontic Department

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 1059

Email address

m.k.soltani@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2014-05-10, 1393/02/20

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of treatment results and patient satisfaction of Classic Twin-block and Clear Twin-block in classII, div 1 malocclusions.

Public title

Comparison of performance of two kinds of lower jaw growth stimulator device in patients with deficiency in lower jaw growth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 8 to 11 years old; overjet of 4 to 8 millimeter; class II, division 1 malocclusion with ANB angle greater than 3 degree; Frankfort mandibular angle between 20 to 25 degree; being in cervical vertebral maturation stage of 1 to 3. Exclusion criteria: craniofacial syndromes; history of trauma to jaws; history of orthodontic treatment or premolar extraction.

Age

From **8 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

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

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

City

Hamedan

Postal code

38677-65178

Approval date

2014-03-02, 1392/12/11

Ethics committee reference number

P/16/35/9/4201

Health conditions studied

1

Description of health condition studied

Orthodontic pateints with class II,division 1 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

Patients satisfaction from treatment

Timepoint

4 mounths after beginig of treatment

Method of measurement

Questionarie

Intervention groups

1

Description

Intervention group one: 33 pateints treated with clear twin block functional appliance

Category

Treatment - Devices

2

Description

intervention group two :33 pateints treated with classic 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 Mohammad Karim Soltani

Street address

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

Hamadan
City
Hamedan

m.k.soltani@umsha.ac.ir; mksoltani2002@yahoo.com
Web page address

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 Bashiriyani

Street address

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

City

Hamedan

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 Mohammad Karim Soltani

Position

Assistant professor

Other areas of specialty/work

Street address

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

City

Hamedan

Postal code

38677-65178

Phone

00898118381059

Fax

+98 81 1838 1085

Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Dr Mohammad Karil Soltani

Position

Assistant professor

Other areas of specialty/work

Street address

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

City

Hamedan

Postal code

38677-65178

Phone

+98 81 1838 1059

Fax

+98 81 1838 1085

Email

m.k.soltani@umsha.ac.irm; ksoltani2002@yahoo.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 Mohammad Karim Soltani

Position

Assistant professor

Other areas of specialty/work

Street address

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

City

Hamedan

Postal code

38677-65178

Phone

+98 81 1838 1059

Fax

+98 81 1838 1085

Email

m.k.soltani@umsha.ac.ir; mksoltani2002@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