

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the treatment effects of the Twin Block appliance in different cervical vertebral maturation stages amongst patients with mandibular retrognathism referring to an orthodontics office in Kerman, 2017

Protocol summary

Summary

The main objective of this study is to evaluate the treatment effects of Twin Block appliance amongst patients with different cervical vertebral maturation stages. The designed clinical trial has no control group and the effects of intervention on each patient before and after treatment are compared with himself. Among patients who come to one of the private orthodontic treatment centers in Kerman, patients with mandibular retrognathism are selected randomly based on the aforementioned inclusion and exclusion criteria. The patients with skeletal and dental class II relationship are from the inclusion criteria in this study who have mandibular retrognathism. Patients who do not have full cooperation in using the device for at least 16 hours a day are excluded. The sample size estimated for this study is 46 people. First, the alignment of the upper jaw anterior teeth is performed. Having eliminated the dental interferences, the appliance is delivered to the patient. The device will be used as long as the patient's overjet reaches zero, and afterwards by applying lateral cephalographs which are prepared before and after the treatment, dental effects of the treatment, such as changes in IMPA angle and skeletal effects like changes in ramus length in different stages of cervical vertebral maturation are studied and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017101036705N1**

Registration date: **2017-11-09, 1396/08/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-09, 1396/08/18

Registrant information

Name

Parisa Kalantari khandani

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the treatment effects of the Twin Block appliance in different cervical vertebral maturation stages amongst patients with mandibular retrognathism referring to an orthodontics office in Kerman, 2017

Public title

Treatment effects of Twin Block appliance in different cervical vertebral maturation stages amongst patients with mandibular retrognathism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Subjects with bilateral molar and canine class II relationship; Skeletal class II relationship measured on cephalometric radiograph (ANB > 3.5); Mandibular retrognathism measured on cephalometric radiograph (SNB<78); Patients with normal or decreased U1-SN angle; Patients of growing age (9-16 years) who were in CS-2, CS-3 and CS-4 of cervical vertebral maturation stage, according to Baccetti et al Exclusion criteria: Patients with any craniofacial anomaly or syndrome; Noncompliant patients who failed to wear the appliance for more than 16hours/day ; Subjects with history of orthodontic treatment.

Age

From **9 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

N/A

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

Kerman University of Medical Sciences

Street address

Next to Shafa hospital, End of Shafa St, Jomhour
Blvd, Kerman, Iran

City

Kerman

Postal code

Approval date

2017-10-31, 1396/08/09

Ethics committee reference number

IR.KMU.REC.1396.1585

Health conditions studied

1

Description of health condition studied

Mandibular retrognathism

ICD-10 code

K07.1

ICD-10 code description

Anomalies of jaw-cranial base relationship

Primary outcomes

1

Description

Mandibular Ramus Length

Timepoint

Pre intervention and Post intervention

Method of measurement

Evaluation of lateral cephalometry

2

Description

SNA angle

Timepoint

Pre intervention and Post intervention

Method of measurement

Evaluation of lateral cephalometry

3

Description

SNB angle

Timepoint

Pre intervention and Post intervention

Method of measurement

Evaluation of lateral cephalometry

4

Description

ANB angle

Timepoint

Pre intervention and Post intervention

Method of measurement

Evaluation of lateral cephalometry

5

Description

GoGn-SN angle

Timepoint

Pre intervention and Post intervention

Method of measurement

Evaluation of lateral cephalometry

6

Description

Co-A distance

Timepoint

Pre intervention and Post intervention
Method of measurement
Evaluation of lateral cephalometry

7

Description

Co-Gn distance

Timepoint

Pre intervention and Post intervention

Method of measurement

Evaluation of lateral cephalometry

8

Description

Go-Gn distance

Timepoint

Pre intervention and Post intervention

Method of measurement

Evaluation of lateral cephalometry

9

Description

U1-SN angle

Timepoint

Pre intervention and Post intervention

Method of measurement

Evaluation of lateral cephalometry

10

Description

IMPA angle

Timepoint

Pre intervention and Post intervention

Method of measurement

Evaluation of lateral cephalometry

Secondary outcomes

1

Description

SNA angle

Timepoint

Pre and Post treatment

Method of measurement

Evaluation of lateral cephalometry

2

Description

SNB angle

Timepoint

Pre and Post treatment

Method of measurement

Evaluation of lateral cephalometry

3

Description

ANB angle

Timepoint

Pre and Post treatment

Method of measurement

Evaluation of lateral cephalometry

4

Description

Go-Gn angle

Timepoint

Pre and Post treatment

Method of measurement

Evaluation of lateral cephalometry

5

Description

Co-A distance

Timepoint

Pre and Post treatment

Method of measurement

Evaluation of lateral cephalometry

6

Description

Co-Gn distance

Timepoint

Pre and Post treatment

Method of measurement

Evaluation of lateral cephalometry

7

Description

Ramus length

Timepoint

Pre and Post treatment

Method of measurement

Evaluation of lateral cephalometry

8

Description

Go-Gn distance

Timepoint

Pre and Post treatment

Method of measurement

Evaluation of lateral cephalometry

9

Description

U1-SN angle

Timepoint

Pre and Post treatment

Method of measurement

Evaluation of lateral cephalometry

10

Description

IMPA angle

Timepoint

Pre and Post treatment

Method of measurement

Evaluation of lateral cephalometry

Intervention groups

1

Description

Intervention name: Twin Block functional appliance
Intervention Description: This appliance is employed in order to treat mandibular retrognathism. The patient should have full cooperation in using the device and wear the device at least 16 hours a day. The device will be used as long as the patient's overjet is zero, and the treatment effects of intervention is investigated by lateral cephalographs of the patients before and after the treatment. This study does not have a control group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

One of the private clinics in orthodontic treatment in Kerman

Full name of responsible person

Parisa Kalantari Khandani

Street address**City**

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

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Next to Shafa hospital, End of Shafa St, Jomhuri Blvd, Kerman, Iran

City

Kerman

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kerman 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**

Kerman University of Medical Sciences

Full name of responsible person

Parisa Kalantari Khandani

Position

Post graduate student of orthodontics

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Full name of responsible person

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Other areas of specialty/work

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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