Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the treatmaent effects of the Twin Block appliance in different cervical vertebral maturation stages amognst 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

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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 treatmaent effects of the Twin Block appliance in different cervical vertebral maturation stages amognst 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 Excusion 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, Jomhouri 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 Lenght
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 lenght
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
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Amin Aminian
Street address
Next to Shafa hospital, End of Shafa St, Jomhouri 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
Other areas of specialty/work
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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