Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of correlation between Dentoskeletal response of Seifi’s functional appliance and Different development stages of cervical vertebrae in patients with Class II Div1malocclusions

Protocol summary

Study aim

The aim of this study was to investigate the effects of seifi’s functional appliance in before and after the peak of growth mutation in patients with class II deep bite malocclusion in order to define the optimal timing for this type of therapy.

Design

clinical trial , before-after , non-randomised

Settings and conduct

After receiving written consent from their parents, they were treated with seifi's functional appliance for one year. Patient's primary records include lateral cephalometric and panoramic , alginate molds, construction bite, and intra-and extra-oral photographs. After the treatment, new records were collected and analyzed by Dolphin software. Panclherz analysis was used to separat dental and skeletal effect.

Participants/Inclusion and exclusion criteria

Inclusion criteria: class II malocclusion with over jet more than 4 mm; Curve of spee more than 2 mm; ANB more than 4 degree; Division 1; Permanent dentition; Mixed dentition; age range between 8-14 years for girls and 8-15 years for boys; Improve the profile in the state of tooth placement in edge to edge position; Exit criteria: Vertical growth pattern; Severe bone abnormality; Non-cooperative patient; Systemic and syndromic diseases; History of orthodontics; Cephalometric preparation before and after treatment in multiple radiography centers.

Intervention groups

Patients with class II deep bite malocclusion

Main outcome variables

Cephalometric landmarks including angles: SNA, SNB, ANB, SN-GoGn, SN-Npog, U1-L1, MP-FH, L1-MP, U1-SN, U1-FH, L1-FH and linear measurements including OB , OJ, Molar relation, Co-Gn, Co-Go, Na-Me, ANS-Me, S-Go, SGo / NaMe, Co-ANS, L6-MP, Dentition period, CVM.

Pancherz's analysis includes variables of: SP / Olp, Pg / Olp, Ar / Olp, Man length, is / Olp minus SP / Olp, ii / Olp minus Pg / Olp.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181005041240N1**
Registration date: **2018-11-23, 1397/09/02**
Registration timing: **retrospective**

Last update: **2018-11-23, 1397/09/02**
Update count: **0**

Registration date

2018-11-23, 1397/09/02

Registrant information

Name

maryam ataee

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 26 4426 8249

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ataee_m@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-02-09, 1394/11/20

Expected recruitment end date

2017-06-10, 1396/03/20

Actual recruitment start date

2016-02-09, 1394/11/20

Actual recruitment end date
2017-06-10, 1396/03/20
Trial completion date
2018-06-20, 1397/03/30

Scientific title
Assessment of correlation between Dentoskeletal response of Seifi’s functional appliance and Different development stages of cervical vertebrae in patients with Class II Div1malocclusions

Public title
Assessment theeEffect of Seifi’s functional appliance in Different Stages of Skeletal development
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
class II malocclusion with over jet more than 4 mm Curve of spee more than 2 mm Deep bite more than 4 mm ANB more than 4 degree Division 1 permanent dentition mixed dentition age range between 8-14 years for girls and 8-15 years for boys Improve the profile in the state of tooth placement in edge to edge position
Exclusion criteria:
Vertical growth pattern Severe bone abnormality Non-cooperative patient Systemic and syndromic diseases History of orthodontics Cephalometric preparation before and after treatment in multiple radiography centers
Age
From **8 years** old to **15 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **26**
Actual sample size reached: **26**
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
Ethics committee of shahid beheshti University of Medical Sciences
Street address
No. 171, First Eskan Alley., Eskan Ave.
City
Hashtgerd new city
Province
Alborz
Postal code
3336117887
Approval date
2016-06-03, 1395/03/14
Ethics committee reference number
IR.SBMU.RIDS.REC.1395.358

Health conditions studied

1

Description of health condition studied
class II div 1 deep bite malocclusion
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
over jet more than 4 mm
Timepoint
measure over jet at the beginning of the study (before the intervention) and 12 months after using the functional appliance
Method of measurement
Measure the distance between the mandibular incisor teeth with incisal edge of maxillary central tooth

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: seifi's functional appliance consisted of maxillary and mandibular removable appliances. the mandibular appliance consisted of incisor clasp on mandibular incisors for retention, an acrylic cap covering incisors and an extension of a lingual flange to mandibular firs molars with no retentive element on posterior teeth to let them erupt independently . the height of the acrylic cap was determined by thickness of construction bite and was limited to the incisal edge of the maxillary incisors. the maxillary appliance consisted of a modify Hawley appliance with the retentive part on posterior teeth, mid palatal screw, an acrylic vertical plate, which fitted back to the guiding plate of lower acrylic cap and a double labial bow was use in cases of maxillary incisors proclination.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Orthodontics,Shahid Beheshti Dental School
Full name of responsible person
maryam ataee
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Daneshju Blvd., Shahid Chamran Highway., shahid beheshti dental school
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Maryam Ataee
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available