

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Assessment of correlation between Dentoskeletal response of Seifi's functional appliance and Different development stages of cervical vertebrae in patients with Class II Div1 malocclusions

#### 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. Pancherz analysis was used to separate 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 / OI<sub>p</sub>, Pg / OI<sub>p</sub>, Ar / OI<sub>p</sub>, Man length, is / OI<sub>p</sub> minus SP / OI<sub>p</sub>, ii / OI<sub>p</sub> minus Pg / OI<sub>p</sub>.

#### 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 atae

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 4426 8249

##### Email address

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 Div1 malocclusions

**Public title**

Assessment the Effect 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 Eskin Alley., Eskin 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 first 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 atae

**Street address**

Daneshju Blvd., Shahid Chamran Highway., shahid beheshti dental school

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 2217 5350

**Email**

ataee\_maryam20@yahoo.com

**Web page address****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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**Province**

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**Postal code**

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+98 21 2243 3455

**Email**

zarghi@sbmu.ac.ir

**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 Atae

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Maryam Atae

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Student

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## Person responsible for updating data

ataee\_m@sbm.ac.ir

### Contact

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Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Maryam Ataee

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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