

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

**“Cephalometric evaluation of dentoalveolar and skeletal changes of upper and lower jaw and pharyngeal airway space changes after growth modification treatments of class III patients in different stages of cervical vertebrae maturation, with Face-mask appliance.”**

### Protocol summary

#### Study aim

Evaluation of dentoalveolar-cephalometric changes of the maxillary and mandibular bones and pharyngeal airways following growth-guided treatments of class 2 patients at different stages of the cervical vertebrae by face mask.

#### Design

A single-blind, interventional study according to Inclusion, Exclusion criteria patient selected, cephalograms of the two groups (1- face mask and 2- face mask and hyrax device) survey before and after treatment. Cephalograms are divided into three groups: CS2, CS1 and CS3 according to the stages of skeletal maturation. Patients' cases reviewed for presence or absence of transverse expansion and expansion protocol also Age - Type of Care - Sex - Type of intraoral appliance of patients checked examining the cephalograms of patients before and after face mask treatment alone or with expansion, to determine the effects of this device

#### Settings and conduct

Shahid Beheshti and Kerman Dental School between 90 - 98 years.

#### Participants/Inclusion and exclusion criteria

Inclusion: 1. Patient with Class 3 Skeletal Problems due to Maxilla Deficiency 2. The patient has no previous orthodontic/orthopedic treatment 3. no systemic disease 4. No new craniofacial abnormality or congenital defects such as thickening 5. Do not have a temporomandibular joint problem 6. Has never had tonsillectomy or adenoids 7. No active periodontal disease Exclusion: 1. Congenital malformations in the craniofacial area 2. Missing or unspecified patient records 3. Differences in the shape of the body of the cervical vertebrae, which include trapezoidal, horizontal, square, and vertical rectangles, respectively. 4. The presence or absence of concussion in the lower port C2, C3, and C4

#### Intervention groups

1-face mask 2- face mask and hyrax expansion device

#### Main outcome variables

Dentoalveolar cephalometric changes of the maxillary and mandibular bone; Changes of the pharyngeal airway space

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20200124046244N1**

Registration date: **2020-07-04, 1399/04/14**

Registration timing: **retrospective**

Last update: **2020-07-04, 1399/04/14**

Update count: **0**

#### Registration date

2020-07-04, 1399/04/14

#### Registrant information

##### Name

shekoofeh shaykhian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3243 4895

##### Email address

shekoofehshaykhian@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2011-03-20, 1389/12/29  
**Expected recruitment end date**  
2019-12-19, 1398/09/28  
**Actual recruitment start date**  
2011-09-22, 1390/06/31  
**Actual recruitment end date**  
2019-12-20, 1398/09/29  
**Trial completion date**  
2019-12-21, 1398/09/30

#### Scientific title

“Cephalometric evaluation of dentoalveolar and skeletal changes of upper and lower jaw and pharyngeal airway space changes after growth modification treatments of class III patients in different stages of cervical vertebrae maturation, with Face-mask appliance.”

#### Public title

“Cephalometric evaluation of dentoalveolar and skeletal changes of upper and lower jaw and pharyngeal airway space changes after growth modification treatments.”

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

The patient has no grade 3 skeletal problem due to maxillary dysfunction The patient has no previous orthodontic / orthopedic treatment No systemic disease No new craniofacial anomaly or congenital defects such as thickening Do not have a temporomandibular joint problem The patient has not had tonsillectomy or adenoids in the past No active periodontal disease

##### Exclusion criteria:

Congenital malformations in the craniofacial region Missing or unspecified patient records Differences in the shape of the cervical vertebrae, which include trapezoidal, horizontal, square and vertical rectangles, respectively. The presence or absence of concussion in the lower port C2, C3 and C4

#### Age

From **8 years** old to **14 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Outcome assessor

#### Sample size

Target sample size: **42**

Actual sample size reached: **54**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

Residents are not aware of the type of treatment performed.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Kerman Research

##### Street address

Vice-chancellor for Research and Technology, Ibn Sina Street, Somayyeh (Tahmasb Abad) Kerman, Iran

##### City

kerman

##### Province

Kerman

##### Postal code

7619813159

#### Approval date

2020-02-17, 1398/11/28

#### Ethics committee reference number

IR.KMU.REC.1398.456

## Health conditions studied

### 1

#### Description of health condition studied

Class 3 skeletal malocclusion

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Evaluation of dentoalveolar cephalometric - upper and lower jaw bone

#### Timepoint

Before and after treatment

#### Method of measurement

Pre- and post-cephalograms of patients are manually performed by an orthodontic resident.

### 2

#### Description

and pharyngeal airway space changes

#### Timepoint

Before and after treatment

#### Method of measurement

By Auto CAD 2018 software

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Face mask group 2- face mask device and hyrax expansion device

### Category

Treatment - Devices

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

School of Dentistry

#### Full name of responsible person

Dr Ali Eskandarizadeh

#### Street address

Shafa Ave, School of Dentistry - Kerman, Iran

#### City

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#### Province

Kerman

#### Postal code

7618759689

#### Phone

+98 34 3211 9021

#### Email

dentistryschool@kmu.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Kerman University of Medical Sciences

#### Full name of responsible person

Dr Abbas Pardakhrati

#### Street address

Vice-chancellor for Research and Technology, Ebneh Sina Ave, Somayyeh (Tahmasb Abad), Kerman, Iran

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#### Postal code

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#### Phone

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#### Email

kmu\_research@yahoo.com

### 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

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

Kerman University of Medical Sciences

#### Full name of responsible person

DR Amin Aminian

#### Position

Assistant Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Dentistry

#### Street address

Shafa Ave, Dental School - Kerman, Iran

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mfaminian@yahoo.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Kerman University of Medical Sciences

#### Full name of responsible person

Amin Aminian

#### Position

Assistant Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Dentistry

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Shekoofeh Shaykhian

**Position**

Orthodontics resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Shafa Ave, Dental School - Kerman, Iran

**City**

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**Province**

Kerman

**Postal code**

7618759689

**Phone**

+98 34 3211 9021

**Email**

shekoofehshaykhian@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

As the result of the data will be published as article , it is not necessary to publish the data file

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available