Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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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

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Province

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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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