

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Capnographic and pulse oximetric comparison of breathing function changes in patients with mandibular deficiency before and after treatment with a removable functional appliance

Protocol summary

Study aim

The aim of this study is to compare the changes in respiratory function in patients with mandibular deficiency before and after treatment with a removable functional appliance using capnography and pulse oximetry methods

Design

This semi experimental prospective study will be carried out on 22 patients aged between 8 to 15 years old. Sampling method is purposefully non randomized.

Settings and conduct

This semi experimental prospective study will be carried out on 22 patients aged between 8 to 15 years admitted to the Faculty of Dentistry of Ahvaz Jundishapur University of Medical Sciences. The end-tidal concentration of carbon dioxide is recorded by capnograph device. Patients sit on a chair and nasal canola is placed on the nose. Exhaled carbon dioxide levels will be recorded for 6 minutes. Pulse oximetry will be carried out simultaneously using a probe that is placed on index finger. Before starting treatment and after treatment with functional appliance for 6 months (T1) PET CO₂ and Spo₂ are measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: skeletal class two division one malocclusion with normal upper jaw (SNA=80-84) and deficient mandible (SNB <77). Overjet more than 5 mm. Exclusion criteria: history of previous orthodontic treatment; systemic disease that affect general and skeletal growth; craniofacial syndromes; respiratory problems not related to orthodontics.

Intervention groups

In this study a removable functional appliance known as activator is used to treat patients. The end-tidal concentration of carbon dioxide is recorded by capnograph device. Patients sit on a chair and nasal canola is placed on the nose. Exhaled carbon dioxide

levels will be recorded for 6 minutes. Pulse oximetry will be carried out simultaneously using a probe that is placed on index finger.

Main outcome variables

End tidal carbon dioxide, oxygen

General information

Reason for update

Acronym

Capnographic and pulse oximetric comparison of breathing function changes in patients with mandibular

IRCT registration information

IRCT registration number: **IRCT20160927030014N2**

Registration date: **2020-05-25, 1399/03/05**

Registration timing: **retrospective**

Last update: **2020-05-25, 1399/03/05**

Update count: **0**

Registration date

2020-05-25, 1399/03/05

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 7076

Email address

eini.e@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2016-11-21, 1395/09/01
Actual recruitment start date
2016-10-22, 1395/08/01
Actual recruitment end date
2016-11-21, 1395/09/01
Trial completion date
2017-05-22, 1396/03/01

Scientific title

Capnographic and pulse oximetric comparison of breathing function changes in patients with mandibular deficiency before and after treatment with a removable functional appliance

Public title

Effect of functional orthopedic appliance on patients with mandibular deficiency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Skeletal class two division one malocclusion with normal upper jaw (SNA=80-84) and deficient mandible (SNB <77). Overjet more than 5 mm

Exclusion criteria:

History of previous orthodontic treatment Systemic disease that affect general and skeletal growth Craniofacial syndromes Respiratory problems not related to orthodontics

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: **22**

Actual sample size reached: **22**

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 ahvaz jundishapur univercity of medical sciences

Street address

Golestan blvd

City

Ahvaz

Province

Khuzestan

Postal code

61357

Approval date

2015-09-21, 1394/06/30

Ethics committee reference number

IR.AJUMS.REC.1394.643

Health conditions studied

1

Description of health condition studied

Mandibular deficiency

ICD-10 code

K07.1

ICD-10 code description

Anomalies of jaw-cranial base relationship

Primary outcomes

1

Description

End-Tidal Carbon Dioxide

Timepoint

before intervention, six months after intervention

Method of measurement

Capnography device

2

Description

Percent of blood oxigen saturation

Timepoint

Before intervention, six months after intervention

Method of measurement

Pulse oximetry device

Secondary outcomes

1

Description

Respiration rate

Timepoint

The beginning of the study, six months later

Method of measurement

Capnograph device

Intervention groups

1

Description

In this study, the effect of treatment with an activator functional device (which used for stimulating the growth of the mandible) was assessed on the level of end tidal carbon dioxide and percentage of oxygen saturation in patient with mandibular deficiency. End tidal carbon dioxide and percentage of oxygen saturation were measured with a Capnograph and pulse oximeter devices Respectively before treatment and six months after treatment.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthodontics department, faculty of dentistry, ahvaz jundishapur university of medical sciences

Full name of responsible person

ebrahim eini

Street address

Dey street

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eini.e@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Nader Saki

Street address

Deputy of research development of ahvaz jundishapur university of medical sciences

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Ebrahim Eini

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information on the main consequence

When the data will become available and for how long

Access periods starting 1 month after the publication of results

To whom data/document is available

Everyone

Under which criteria data/document could be used

In all circumstances

From where data/document is obtainable

ebrahim eini 09163644166

What processes are involved for a request to access data/document

It will be sent within a week after the call

Comments