

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of apnea-hypopnea index change and the incidence of obstructive sleep apnea in patients with class III skeletal deformity, after mandibular setback surgery with ApneaLink device.

Protocol summary

Study aim

Determining the incidence of obstructive sleep apnea and changes in the apnea-hypopnea index in patients with class III skeletal deformity after mandibular setback surgery with ApneaLink device

Design

This study will be performed as a double-blinded quasi-experimental. This is before-after interventional pilot research which would be executed on 10 patients for evaluation of apnea/hypopnea index by Apnea-link device. The outcome assessor and data analyzer will be blinded.

Settings and conduct

Oral and maxillofacial surgery department of Qaem hospital, Mashhad. The outcome assessor and the data analyzer will be blinded.

Participants/Inclusion and exclusion criteria

All of the non-smoker patients with skeletal class III deformities with the age range of 18-30 years old who candidate for orthogenetic surgery; with ASA 1 or 2; without congenital syndromes; without a history of respiratory diseases like rhinitis, asthma, bronchitis, would be included in our study. Exclusion criteria: Patients who would not attend for follow up

Intervention groups

The intervention in this study is mandibular setback surgery using a bilateral sagittal split osteotomy (BSSO) and maxillary advancement using Lefort 1 osteotomy. As a result, this study has no control group.

Main outcome variables

Apnea-hypopnea Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150613022697N11**

Registration date: **2021-02-23, 1399/12/05**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-23, 1399/12/05**

Update count: **0**

Registration date

2021-02-23, 1399/12/05

Registrant information

Name

Sahand Samiee rad

Name of organization / entity

mashhad dental school, oral and maxillofacial department

Country

Iran (Islamic Republic of)

Phone

+98 51 3883 7289

Email address

samieerads@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of apnea-hypopnea index change and the

incidence of obstructive sleep apnea in patients with class III skeletal deformity, after mandibular setback surgery with ApneaLink device.

Public title

Evaluation of the effect of mandibular setback surgery on Apnea-hypopnea Index with ApneaLink device.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Non-smoker patients between the ages of 18 and 40
Patients with skeletal class 3 deformity who are candidates for orthognathic mandibular setback surgery by bilateral sagittal split osteotomy (BSSO) BMI less than 30 kg/m² ASA 1,2

Exclusion criteria:

Patients with a history of respiratory diseases like rhinitis, asthma, bronchitis. Patients with a history of maxillofacial congenital syndromes .

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the outcome assessor and data analyzer will not know about the study groups. Regarding the assessor, who is a pulmonologist will not be aware of the surgical intervention and the amount of mandibular movement in millimeters. The data analyzer will be blinded and all data will be provided in the form of coding to him.

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad university of medical

sciences

Street address

Ghoreishi building, Daneshgah avenue.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2020-12-16, 1399/09/26

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1399.109

Health conditions studied

1

Description of health condition studied

Obstructive sleep apnea

ICD-10 code

G47.33

ICD-10 code description

Obstructive sleep apnea (adult) (pediatric)

Primary outcomes

1

Description

Apnea-hypopnea Index

Timepoint

Before surgery, one month and three months after surgery

Method of measurement

ApneaLink device

2

Description

Obstructive Sleep apnea recovery

Timepoint

Before surgery, one month and three months after surgery

Method of measurement

En Apnea link device measurement.

Secondary outcomes

empty

Intervention groups

1

Description

The intervention in this study is mandibular setback surgery by bilateral sagittal split osteotomy (BSSO) and maxillary advancement using Lefort 1 osteotomy.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral and maxillofacial surgery department of Qaem hospital, Mashhad

Full name of responsible person

Sahand Samieerad

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Ahmadabad boulv, Mashhad Qaem hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Sahand Samieerad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Mashhad University of Medical Sciences

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Ali Labafchi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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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

All collected data would be shared for all researchers after the participants were unidentified.

When the data will become available and for how long

The access to data will be started 6 months after publication

To whom data/document is available

The data would only be available for people working in academic institutions.

Under which criteria data/document could be used

It is allowed to use the data for meta-analysis and systematic reviews.

From where data/document is obtainable

The data can be obtained via email, from the corresponding researches (Dr Sahand samiee rad). E-mail: samieerads@mums.ac.ir

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

The new research proposal and the processes details should be e-mailed to the corresponding researcher in order to get the access permission

Comments