

# 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/m<sup>2</sup> 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

**Street address**

Ahmadabad boulv, Mashhad Qaem hospital

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samieerads@mums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Ghoreishi building, Daneshghah avenue

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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

**Street address**

oral and maxillofacial surgery department, Mashhad dental school, Vakil abad street.

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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**

Dentistry

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**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**