

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### The evaluation of obstructive sleep apnea incidence after mandibular setback orthognathic surgery in patients with skeletal class III deficiencies, by combination of Epworth, Berlin and STOP-BANG questionnaires.

#### Protocol summary

##### Study aim

The evaluation of obstructive sleep apnea incidence after mandibular setback orthognathic surgery based on jaw movement amounts, in patients with skeletal class III deficiencies, by combination of STOP-BANG, Berlin and Epworth sleep scale questionnaires.

##### Design

This study will be performed as a double blinded quasi-experimental. This is a before-after interventional research which would be executed on 60 patients with skeletal class 3 deficiency for evaluation of obstructive sleep apnea incidence by combination of STOP-BANG, Berlin and Epworth questionnaires.

##### Settings and conduct

Mashhad dental school, oral and maxillofacial department

##### Participants/Inclusion and exclusion criteria

All of the patients with class III deformities with the age range of 18-30 years old who candidate for orthogenetic surgery; with ASA 1 or 2; without congenital syndroms; without the history of respiratory diseases like rhinitis, asthma , bronchitis, would be included in our study.

##### Intervention groups

Mandibular setback surgery with or without maxillary advancement. No control group is available in this study.

##### Main outcome variables

Postoperative obstructive sleep apnea

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150613022697N5**

Registration date: **2018-11-18, 1397/08/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-11-18, 1397/08/27**

Update count: **0**

##### Registration date

2018-11-18, 1397/08/27

##### 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

2018-10-02, 1397/07/10

##### Expected recruitment end date

2019-09-21, 1398/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The evaluation of obstructive sleep apnea incidence after mandibular setback orthognathic surgery in patients with skeletal class III deficiencies, by combination of Epworth, Berlin and STOP-BANG questionnaires.

## Public title

The evaluation of obstructive sleep apnea incidence after mandibular setback surgery by combination of questionnaires.

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

All of the patients with class III deformities with the age range of 18-30 years old who candidate for orthogenetic surgery Patients with ASA 1 or 2

### Exclusion criteria:

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

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Investigator
- Data analyser

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Person who would be responsible for information collection and also who investigate and analyse the data are blind.

## Placebo

Not used

## Assignment

Other

## Other design features

This study will be a quasi-experimental and before-after interventional research.

## 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

2018-10-28, 1397/08/06

#### Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1397.071

## 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)

### 2

#### Description of health condition studied

class III malocclusion

#### ICD-10 code

M26

#### ICD-10 code description

Dentofacial anomalies [including malocclusion]

## Primary outcomes

### 1

#### Description

Obstructive sleep apnea incidence.

#### Timepoint

1 week before surgery - 1 month and 3 month postoperatively.

#### Method of measurement

STOP-BANG, Berlin and Epworth questionnaires.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The amount of posterior movement of mandible and chin (mm), following the mandibular setback sagittal osteotomy surgery.

#### Category

Treatment - Surgery

### 2

#### Description

Control group: Without posterior movement of mandible and chin , following the mandibular setback sagittal osteotomy surgery.

#### Category

Treatment - Surgery

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Ghaem hospital

**Full name of responsible person**

Sahand Samiee Rad

**Street address**

Mashhad dental school, Vakil Abad street.

**City**

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**Postal code**

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**Email**

samieerads@mums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Saeed Eslami

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Ghoreishi building, Daneshghah avenue.

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eslamis@mums.ac.ir

**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**

30

**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 Samiee rad

**Position**

Assistant 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

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Sahand Samiee rad

**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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Niusha Yavari

**Position**

student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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

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**Email**

niusha.yavari@yahoo.com

**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 unindetified data would be shared for all researchers.

**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 corresponding researcher in order to get the access permission.

**Comments**