

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 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 orthognathic 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, Daneshghah 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

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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 Saeed Eslami

Street address

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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

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

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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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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 unidentifiable 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