

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Assesment the changes of echocardiography- systmic BP- AHI and CRP and blood uric acid levels in patients with mild to moderate obstructive sleep apnea before and after sleep surgery.

Protocol summary

Summary

The sleep apnea is a common disease.This disease is a transient respiratory arrest in the sleep.In our semiexperimental study the main goal is assesment of the changes in echocardiography- hypertension- AHI and the levels of CRP- blood uric acid in the patient with mild to moderate obstructive sleep apnea before and after sleep surgery.Our study is nonrandomized and without control with placebo.The main inclusion criteria is AHI>15 or AHI<40 with severe daily somnolence.The main exclusion criteria is previous palatal surgery or head and neck radiation or facial anomaly.The sample size is 23 person and the method of surgery is Uvulopalatopharyngoplasty based on observation of significant retropalatal collapse in DISE.The primary outcome of surgery is improvment of life style due to sleep and reduction of cardiovascular accident result from sleep apnea.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010831822N1**
Registration date: **2017-05-02, 1396/02/12**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-02, 1396/02/12

Registrant information

Name

Kayvan Aghazadeh

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research and technology of Tehran University Of Medical Sciences.

Expected recruitment start date

2017-04-03, 1396/01/14

Expected recruitment end date

2019-04-03, 1398/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assesment the changes of echocardiography- systmic BP- AHI and CRP and blood uric acid levels in patients with mild to moderate obstructive sleep apnea before and after sleep surgery.

Public title

Assesment the changes of echocardiography- systmic BP- AHI and CRP and blood uric acid levels in patients with mild to moderate obstructive sleep apnea before and after sleep surgery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: OSA basd on polysomnogaghy; the patient with OSA that candidate for sleep surgery;

AHI>15 or AHI<40 with severe daily somnolence; The age between 30-65. The main exclusion criteria: previous palatal surgery; head and neck radiation; facial anomaly or craniofacial syndrome.

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **23**

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 Tehran University Of Medical
Sciences

Street address

Kshavarz boultar. qods street.Morality organization of
TUMS

City

Tehran

Postal code

Approval date

2017-01-31, 1395/11/12

Ethics committee reference number

IR.TUMS.VCR.REC.1395.1595

Health conditions studied

1

Description of health condition studied

Obstructive sleep apnea

ICD-10 code

J30-J39

ICD-10 code description

Other diseases of upper respiratory tract

Primary outcomes

1

Description

Blood pressure

Timepoint

Before and one month after intervention

Method of measurement

Holter monitoring

2

Description

Ejection Fraction

Timepoint

Before and one month after intervention

Method of measurement

Echocardiography

3

Description

Sleep Condition

Timepoint

Before and one month after intervention

Method of measurement

Polysomnography

Secondary outcomes

1

Description

CRP

Timepoint

Before and one month after intervention

Method of measurement

Blood sample test

2

Description

Serum uric acid

Timepoint

Before and one month after intervention

Method of measurement

Blood sample test

3

Description

BMI

Timepoint

Before and one month after intervention

Method of measurement

Proportion of height to (weight square)

Intervention groups

1

Description

Uvulopalatopharyngoplasty is the one of types of open procedure that reduces the shape and size of uvula - soft palate and pharynx and includes resection of uvula - tonsils and the part of soft palate and oral roof and indicates for significant retropalatal collapse.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralam hospital

Full name of responsible person

Dr Faezeh Dehsa

Street address

Tehran - saadi shomali street - Amiraalam hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for researches and technology

Full name of responsible person

Dr. Masoud Younesian

Street address

Sixth floor, Main Building, Tehran University of Medical Sciences, Kshavarz blvd.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-chancellor for researches and technology

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Amiraalam hospital

Full name of responsible person

Faezeh Dehsara

Position

ENT resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

phD of physiology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty