Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

Positive airway pressure (PAP) therapy and its impact on the components of metabolic syndrome in obstructive sleep apnea (OSA) patients

Protocol summary

Summary

Objectives: The effect of positive airway pressure (PAP) therapy on the components of metabolic syndrome in obstructive sleep apnea (OSA) Design: The study population consists of patients with clinical indication for PAP therapy. The sample is 40 patients of Sleep Clinic in Baharlooo Hospital. This study does not have a control group. Setting and conduct: The patients referred to the Sleep Clinic complete the related questionnaires. After history taking and physical exam, a polysomnography will be performed. Patients with clinical indication for PAP therapy will be admitted to participate in the study and will be reevaluated in 3 months. Participants: Inclusion criteria consist of adult patients with OSA and clinical indication for PAP therapy. Exclusion criteria consist of pregnancy, cardiopulmonary disorder, upper airway cancer or surgery, change or new administration of drug for hyperlipidemia, hypertension and diabetes mellitus. Intervention: PAP therapy Main outcome measures: blood pressure, abdominal circumference and other anthropometric indexes, sex, age, fasting blood sugar (FBS), high density lipoprotein (HDL), triglyceride, liver and kidney tests, 25 hydroxy vitamin D3, Erythrocyte sedimentation rate (ESR), c reactive protein (CRP), and other complementary tests

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012832249N1**
Registration date: **2017-04-10, 1396/01/21**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-04-10, 1396/01/21

Registrant information

Name
Zahra Banafsheh Alemohammad
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Grant from Tehran University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Positive airway pressure (PAP) therapy and its impact on the components of metabolic syndrome in obstructive sleep apnea (OSA) patients

Public title

The effect of positive airway pressure (PAP) therapy on the components of metabolic syndrome in obstructive sleep apnea (OSA)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria consist of adult patients with OSA and clinical indication for PAP therapy. Exclusion criteria

consist of pregnancy, cardiopulmonary disorder, upper airway cancer or surgery, change or new administration of drug for hyperlipidemia, hypertension and diabetes mellitus.

Age
From **14 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

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
Tehran University of Medical Sciences, Ghods Ave., Keshavarz Blvd.

City
Tehran

Postal code

Approval date
2017-01-28, 1395/11/09

Ethics committee reference number
IR.TUMS.VCR.REC.1395.1549

Health conditions studied

1

Description of health condition studied
Obstructive Sleep Apnea

ICD-10 code
G47.3

ICD-10 code description
A disorder characterized by cessation of breathing for short periods during sleep

Primary outcomes

1

Description
Blood pressure

Timepoint
before treatment and 3 months following beginning of the treatment

Method of measurement
Sphygomanometer

2

Description
high density lipoprotein

Timepoint
before treatment and 3 months following beginning of the treatment

Method of measurement
Direct Enzymatic Colorimetric Method

3

Description
fasting blood sugar

Timepoint
before treatment and 3 months following beginning of the treatment

Method of measurement
glucose oxidase assay

4

Description
triglyceride

Timepoint
before treatment and 3 months following beginning of the treatment

Method of measurement
lipase peroxidase colorometric

5

Description
Abdominal Circumference

Timepoint
before treatment and 3 months following beginning of the treatment

Method of measurement
Metre

Secondary outcomes

1

Description
weight

Timepoint
before treatment and 3 months following beginning of the treatment

Method of measurement
scale

2

Description
Body Mass Index
Timepoint
before treatment and 3 months following beginning of the treatment
Method of measurement
scale and stadiometer

3

Description
c reactive protein
Timepoint
before treatment and 3 months following beginning of the treatment
Method of measurement
quantitative latex immunoturbidimetric assay

4

Description
Erythrocyte sedimentation rate
Timepoint
before treatment and 3 months following beginning of the treatment
Method of measurement
the Westergren method (therma)

5

Description
alkaline phosphatase
Timepoint
before treatment and 3 months following beginning of the treatment
Method of measurement
nitrophenyl phosphate kinetic

6

Description
complete blood count
Timepoint
before treatment and 3 months following beginning of the treatment
Method of measurement
cell counter

7

Description
hemoglobin A1c
Timepoint
before treatment and 3 months following beginning of the treatment
Method of measurement
High Performance Liquid Chromatography

8

Description
alanine amino transferase
Timepoint
before treatment and 3 months following beginning of the treatment
Method of measurement
NADH Kinetic UV

9

Description
aspartate amino tranferase
Timepoint
before treatment and 3 months following beginning of the treatment
Method of measurement
NADH Kinetic UV

10

Description
uric acid
Timepoint
before treatment and 3 months following beginning of the treatment
Method of measurement
enzymatic colorimetric

11

Description
cholesterol
Timepoint
before treatment and 3 months following beginning of the treatment
Method of measurement
cholestrol oxidase peroxidase colorimetric

12

Description
25 hydroxy vitamin D3
Timepoint
before treatment and 3 months following beginning of the treatment
Method of measurement
High Performance Liquid Chromatography

13

Description
creatinine
Timepoint
before treatment and 3 months following beginning of the treatment
Method of measurement
jaffe kinetic colorimetric

14

Description
blood urea nitrogen
Timepoint
before treatment and 3 months following beginning of the treatment

Method of measurement
Urease GLDH Kinetic

15

Description
low density lipoprotein
Timepoint
before treatment and 3 months following beginning of the treatment
Method of measurement
Direct Enzymatic colorimetric

Intervention groups

1

Description
PAP therapy
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Sleep Clinic of Baharloo Hospital
Full name of responsible person
Mohammad Mehraban
Street address
Baharloo Hospital, Behdari St., Rahahan Sq.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Masuod Yoonesian
Street address
sixth floor, Tehran University of Medical Sciences, Ghods Ave., Keshavarz 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 research, Tehran University of Medical Sciences
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
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Mehraban
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Position

Sleep Medicine Fellowship

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