

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 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 Baharloo 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

Country

Iran (Islamic Republic of)

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+98 21 5567 7333

Email address

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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 colorimetric

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 transferase

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

cholesterol 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

Position

Occupational Medicine Resident

Other areas of specialty/work**Street address**

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Full name of responsible person

Zahra Banafsheh Alemohammad

Position

Sleep Medicine Fellowship

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Tehran University of Medical Sciences

Full name of responsible person

Zahra Banafsheh Alemohammad

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