

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of continuous positive airway pressure in the treatment of refractory hypertension in patients with sever obstructive sleep apnea

Protocol summary

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Summary

The aim of this study is to compare continuous positive airway pressure with standard treatment in patients with refractory hypertension and sever obstructive sleep apnea (loss of respiratory flow to 50% for more than 10 times/hour and 4% reduction in O2 saturation in pulse oximetry). Patients will be randomly divided to control(losartan 25mg/bid, triamteren-H 50mg/day, amlodipin 5mg/bid, Acetazolamid 250mg/day, fluoxetine 20mg/day) and intervention (losartan 25mg/bid, triamteren-H 50mg/day, amlodipin 5mg/bid and continuous positive airway pressure)groups. All patients will be treated 4 weeks and systolic and diastolic blood pressure will be evaluated 3 times weekly.

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2011-08-21, 1390/05/30

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108167346N1**

Registration date: **2011-12-19, 1390/09/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-19, 1390/09/28

Registrant information

Name

Bahareh Bayat

Name of organization / entity

Arak Univercity of Medical Sences

Country

Iran (Islamic Republic of)

Phone

+98 86 1223 9264

Email address

Scientific title

Effect of continuous positive airway pressure in the treatment of refractory hypertension in patients with sever obstructive sleep apnea

Public title

Effect of continuous positive airway pressure in the treatment of refractory hypertension in patients with sever obstructive sleep apnea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age:40-80; refractory hypertension and severe obstructive sleep apnea(AHI>15) exclusion criteria:central apnea;current severe respiratory disease;functional class:III, IV;pregnancy;secondary hypetension;history of treatment by continuous positive airway pressure.

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Arak University of Medical Sciences

Street address
Arak University of Medical Sciences, Arak, Iran

City
Arak

Postal code

Approval date
2011-07-27, 1390/05/05

Ethics committee reference number
90-111-2

Health conditions studied

1

Description of health condition studied
High blood pressure

ICD-10 code
I10

ICD-10 code description
Essential (primary) hypertension

2

Description of health condition studied
Sleep apnoea

ICD-10 code
G47.3

ICD-10 code description
Sleep apnoea

Primary outcomes

1

Description
Blood Pressure

Timepoint
3 times a week

Method of measurement
mmHg(by mercury barometer)

Secondary outcomes

1

Description
Heart rate

Timepoint
3 times/week

Method of measurement
Beat/min

Intervention groups

1

Description
Control group: losartan 25mg/bid + Triamterene-H 50mg/day + Amlodipine 5mg/bid + Acetazolamid 250mg/day and Fluoxetine 20mg/day

Category
Treatment - Drugs

2

Description
Intervention group: Losartan 25mg/bid + Triamterene-H 50mg/day + Amlodipine 5mg/bid + Nasal CPAP(every night for 4 weeks)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amiralmomenin hospital

Full name of responsible person

Street address
Amiralmomenin hospital, Arak, Iran

City
Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr.Saeed Changizi Ashtiyani

Street address

Office of Vice Chancellor for Research of Arak
University of Medical Sciences, Iran

City

Arak

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Dr. Bahare Bayat

Position

MD

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

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

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Web page address**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