Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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.

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

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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

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
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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

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Name of organization / entity
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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