Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of CPAP on Diastolic function in patients with obstructive sleep apnea in Esfahan in the year 1394

Protocol summary

Summary

Abstract: Disorders are usually related with sleep apnea in patients with cardiovascular problems. Objectives: To determine the effect of continuous positive pressure ventilation on left ventricular diastolic function in patients with obstructive sleep apnea is. Design: This study is a clinical trial. Material and Method: In this study, 32 patients with concurrently obstructive sleep apnea and left ventricular diastolic dysfunction Inclusion criteria: echocardiographic evidence of left ventricular diastolic function disorder; Patients who used continuous positive pressure ventilation for at least an hour to be endured; During the four weeks before starting treatment, the patient does not any changes in the clinical comorbidity. During the four weeks prior to treatment, there is no change in the patient's medications; Young and middle-aged adults. Exclusion criteria: patients who are symptomatic obstructive sleep apnea; Morbid obesity, pregnant or breast feeding women; subjects who had severe heart disease during the past three months; Use less than 3/30 hours of continuous positive pressure ventilation during the night; During the six-month period of treatment, the patient is given a change in medication; Will be Checked by random sampling. Interventions: based on the results of polysomnography and echocardiography of patients underwent a six-month period conditioning continuous positive pressure fall and after completion of the course of treatment again two groups, before and after 6 months of diastolic function of the left ventricle echocardiography

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030622134N3**
Registration date: **2016-06-04, 1395/03/15**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-06-04, 1395/03/15

Registrant information

Name
Mahtab Keshvari
Name of organization / entity
Cardiovascular Institution
Country
Iran (Islamic Republic of)
Phone
+98 913 781 0322
Email address
mkeshvari@crc.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Shahrekord University of Medical Sciences

Expected recruitment start date

2016-02-04, 1394/11/15

Expected recruitment end date

2016-06-04, 1395/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of CPAP on Diastolic function in patients with obstructive sleep apnea in Esfahan in the year 1394

Public title

The effect of continuous ventilation on left ventricular function in patients with obstructive sleep apnea in Isfahan

Purpose
Treatment
Inclusion/Exclusion criteria
Disorders are usually related with sleep apnea in patients with cardiovascular problems. Objectives: To determine the effect of continuous positive pressure ventilation on left ventricular diastolic function in patients with obstructive sleep apnea is. Design: This study is a clinical trial. Material and Method: In this study, 32 patients with concurrently obstructive sleep apnea and left ventricular diastolic dysfunction Inclusion criteria: echocardiographic evidence of left ventricular diastolic function disorder; Patients who used continuous positive pressure ventilation for at least an hour to be endured; During the four weeks before starting treatment, the patient does not any changes in the clinical comorbidity. During the four weeks prior to treatment, there is no change in the patient's medications; Young and middle-aged adults. Exclusion criteria: patients who are symptomatic obstructive sleep apnea; Morbid obesity, pregnant or breast feeding women; subjects who had severe heart disease during the past three months; Use less than 3/30 hours of continuous positive pressure ventilation during the night; During the six-month period of treatment, the patient is given a change in medication; Will be Checked by random sampling. Interventions: based on the results of polysomnography and echocardiography of patients underwent a six-month period conditioning continuous positive pressure fall and after completion of the course of treatment again groups, before and after 6 months of diastolic function of the left ventricle echocardiography
Age
From **25 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **32**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not 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 Isfahan University of Medical Sciences
Street address
Hezar Jerib Ave., Azadi sqr., Isfahan University of medical science, Isfahan, Iran
City
Isfahan
Postal code
009831
Approval date
2016-01-06, 1394/10/16
Ethics committee reference number
IR.MUI.RC. 1394. 394959

Health conditions studied

1

Description of health condition studied
cardiovascular disease
ICD-10 code
I51.6
ICD-10 code description
Cardiovascular accident NOS

2

Description of health condition studied
apnoea
ICD-10 code
G47.3
ICD-10 code description
Sleep apnoea

Primary outcomes

1

Description
Peak E
Timepoint
6 Months after treatment with continuous positive pressure ventilation
Method of measurement
Based on the grading echocardiography

2

Description
Peak A
Timepoint
6 Months after treatment with continuous positive pressure ventilation
Method of measurement
Based on the grading echocardiography

3

Description
E/A Parameter
Timepoint

6 Months after treatment with continuous positive pressure ventilation

Method of measurement

Based on the grading echocardiography

4

Description

Flow propagation velocity

Timepoint

6 Months after treatment with continuous positive pressure ventilation

Method of measurement

Based on the grading echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Patients will be treated for for six months with continuous positive pressure conditioning

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

chamran cardiology hospital

Full name of responsible person

Dr. Hamid Sanei

Street address

Iran, Isfahan, chamran cardiology hospital, Salman-e-Farsi

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mehdi Nematbakhsh

Street address

Hezar Jirib St.

City

Isfahan

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 of Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Ali Yousefi

Position

Resident of cardiology

Other areas of specialty/work

Street address

Hezar Jerib Ave., Azadi sqr., Isfahan University of medical science, Isfahan, Iran

City

Isfahan

Postal code

Phone

+98 31326009615

Fax

Email

dryousefi79@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences, Iran

Full name of responsible person

Dr.Hamid Sanei

Position

cardiologist

Other areas of specialty/work

Street address

Hezar Jerib Ave., Azadi sqr., Isfahan University of medical science, Isfahan, Iran

City

Isfahan

Postal code

Phone

+98 31326009615

Fax

Email

H_sanei@med.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Isfahan Cardiovascular Research Center, Isfahan University of Medical Sciences, Iran

Full name of responsible person
Mahtab Keshvari

Position
Ph.D. Student

Other areas of specialty/work

Street address
Khorram Street, Jomhoori Square

City
Isfahan

Postal code

Phone
+98 313359090

Fax

Email
mahtabkeshvari87@yahoo.com

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