

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

AgeFrom **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