

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effect of continuous positive airway pressure (CPAP) and biphasic Positive Airway Pressure (BiPAP) on hemodynamic parameters in covid-19 patients

Protocol summary

Study aim

Most previous studies on the effects of CPAP and BiPAP masks on hemodynamic status have been performed in patients who usually have relatively stable conditions, and no study has been found comparing the two masks in coronary patients. Evidence suggests that patients Covid-19 sufferers suffer from cardiovascular problems and hemodynamic changes, so in emergencies, the use of respiratory aids with minimal side effects is considered. Because no study was found to compare the hemodynamic effects of CPAP and BiPAP masks on patients with Covid-19, this study was performed.

Design

After approving the proposal and obtaining the permission of the University Ethics Committee, the researcher will go to the hospital and patients with Covid-19 will be selected according to the doctor's diagnosis and laboratory results and based on the inclusion criteria. In this way, the specialist will select patients who need non-invasive ventilation according to the protocol of the Office of Respiratory Failure in Covid-19 of the Ministry of Health. After determining the type of mask, the patient's hemodynamic status (systolic blood pressure, diastolic blood pressure, heart rate) based on the monitor attached to the patient before mask administration, immediately after use and after 1 hour, 6 hours and then daily for up to 3 days at an hour. One person will be examined.

Settings and conduct

Teaching hospitals Associated with Gonabad University of Medical Sciences

Participants/Inclusion and exclusion criteria

need for oxygen and candidate for non-invasive respiratory aid (NIV) according to the doctor (need for intubation No) Exclusion criteria: the need for immediate intubation of the patient

Intervention groups

intervention group with CPAP and intervention group with BiPAP

Main outcome variables

Hemodynamic parameters

General information

Reason for update

Acronym

cbpapc

IRCT registration information

IRCT registration number: **IRCT20210424051061N1**

Registration date: **2021-09-29, 1400/07/07**

Registration timing: **retrospective**

Last update: **2021-09-29, 1400/07/07**

Update count: **0**

Registration date

2021-09-29, 1400/07/07

Registrant information

Name

Raziyeh Nikbeen

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-06-05, 1400/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of continuous positive airway pressure (CPAP) and biphasic Positive Airway Pressure (BiPAP) on hemodynamic parameters in covid-19 patients

Public title

Effect of continuous and biphasic positive airway pressure in patients with Covid

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participate in the study Age 20 -60 y/o No history of cardiovascular disease such as hypertension, liver, kidney according to self-declaration Need to prescribe oxygen and candidate for non-invasive respiratory assistance (NIV) according to physician (no need for intubation) No ban on the use of masks Definitive diagnosis of coronavirus infection by physician and laboratory results

Exclusion criteria:

Need to intubate the patient immediately Awareness level based on the Glasgow scale less than 15 Any change in the patient's condition that affects the course of treatment, for example blood pressure below 90 mmhg despite fluid therapy or the use of vasopressors

AgeFrom **20 years** old to **60 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample sizeTarget sample size: **46****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, first, individuals are entered into the study in an accessible manner based on inclusion and exclusion criteria, and then using permutation blocks in two groups, CPAP mask and BIPAP mask will be allocated. In this method, if we consider the cpap group A, the bipap group B, the 6 possible states will be in the 4 blocks AAB-BBAA-ABAB-BABA-BAAB-ABBA, which will be assigned a number for each block and each The load will be selected by lot and patients will enter the study, respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants, health care personnel (physicians, nurses, physiotherapists, etc.) who are responsible for patient care, used the allocation of the device and did not know the purpose of the study.

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of gonabad University of Medical Sciences

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9P67+R29,Imam Khomeini street, Gonabad, Razavi Khorasan Province

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Approval date

2021-04-21, 1400/02/01

Ethics committee reference number

IR.GMU.REC.1400.006

Health conditions studied**1****Description of health condition studied**

Covid-19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes**1****Description**

Mean score of hemodynamic parameters

Timepoint

Before the mask is prescribed, it will be examined by a person immediately after use and after 1 hour, 6 hours and then daily for up to 3 days at a specific time.

Method of measurement

Patient-connected monitoring device

Secondary outcomes

1

Description

Mean oxygen saturation, mean blood pressure, mean pulse rate

Timepoint

Based on the monitor attached to the patient before the mask is administered, immediately after use and after 1 hour, 6 hours and then daily for up to 3 days at a specific time will be examined by one person.

Method of measurement

Patient-connected monitoring device

Intervention groups

1

Description

Intervention group: In this research, the CPAP device of Saadat and venet manufacturers is used. Using an air pump, the CPAP device transmits airflow to the patient at a pressure set by the mask. The device settings are adjusted by a physician or specialist based on the information contained in the sleep test. These settings include parameters such as the number of apneas; Adjustable pressure range: 20 - 4 cm water; Pressure adjustment: 3 - 0 cm of water; Adjustable initial pressure by the patient; Device settings with buttons; LED lights on the device; Storing, calculating and retrieving information is like the average total treatment hours.

Category

Treatment - Drugs

2

Description

Intervention group: In this research, the BIPAP device of Fisher and Resmed manufacturers is used, which includes a humidifier chamber-hose and mask whose settings include IPAP-EPAP (IPAP applies maximum pressure at the time of inhalation and EPAP minimum pressure at the time of Exhale).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Teaching hospitals related to Gonabad Medical Sciences Hospital

Full name of responsible person

Dr. Kokab Basiri Moghaddam

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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gonabad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

2

Sponsor

Name of organization / entity

Vice Chancellor for Research, Gonabad University of Medical Sciences

Full name of responsible person

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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, Gonabad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code

Not applicable	Only for researchers working in academic and scientific institutions
Data Dictionary	Under which criteria data/document could be used
Not applicable	For research
Title and more details about the data/document	From where data/document is obtainable
All data is potentially shareable after unidentified individuals	Researcher email address
When the data will become available and for how long	What processes are involved for a request to access data/document
After completing the plan	Researcher email address
To whom data/document is available	Comments