Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 Quid-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 Quid-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

Country

Iran (Islamic Republic of)

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Email address

nikbeen.nurse@gmail.com

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
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider

Sample size
Target 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 AABB-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
Street address
9P67+R29,Imam Khomeini street, Gonabad, Razavi Khorasan Province
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Province
Razavi Khorasan
Postal code
5722381522
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 toGonabad Medical Sciences Hospital
Full name of responsible person
Dr. Kokab Basiri Moghaddam
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Sponsors / Funding sources

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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
Dr. Kokab Basiri Moghaddam
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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

Contact
Name of organization / entity
Gonabad University of Medical Sciences
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Person responsible for updating data

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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

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

After completing the plan

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

For research

From where data/document is obtainable

Researcher email address

What processes are involved for a request to access data/document

Researcher email address

Comments