Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative Trial of Intermittent CPAP use in Hypoxemic Patients with COVID-19 infection

Protocol summary

Study aim
To evaluate the role of intermittent use of CPAP (continuous positive pressure ventilation) in hypoxemic patients with CVOID-19 infection requiring at least 10 liters of oxygen.

Design
Two arms parallel-group open-labeled randomized clinical trial

Settings and conduct
The trial will be conducted in the department of General Medicine in the specialized COVID isolation units. This is an open-labeled clinical trial conducted in patients with severe COVID pneumonia requiring oxygen supplementation of 10 liters or more.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1- Age between 18 to 70 years 2- COVID-19 confirmed patients on 10 liters of oxygen or more. Exclusion criteria: 1. Unco-operative patient 2. Pneumothorax 3. Surgical emphysema 4. GCS less than 13 5. Excessive respiratory secretions 6. Shock

Intervention groups
One group (control) will receive the conventional treatment while patients in the intervention group will be put on intermittent CPAP therapy. These patients will be put on CPAP for two hours in the morning and two hours in the evening. Patients will be kept in the intervention group until their oxygen demand reaches 30 liters or more.

Main outcome variables
The primary outcome will be assessed based on the in-hospital mortality. Secondary outcomes will include the duration of hospital stay, patients requiring mechanical ventilation, and patients requiring the use of continuous CPAP or BiPAP therapy.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200723048178N2**
Registration date: **2021-04-28, 1400/02/08**
Registration timing: **prospective**

Last update: **2021-04-28, 1400/02/08**
Update count: **0**

Registration date
2021-04-28, 1400/02/08

Registrant information

Name
Ahmed Farhan

Name of organization / entity
Pakistan Institute of Medical Sciences

Country
Pakistan

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drfarhan992@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-02, 1400/02/12

Expected recruitment end date
2022-05-01, 1401/02/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative Trial of Intermittent CPAP use in Hypoxemic Patients with COVID-19 infection

Public title
Intermittent CPAP in hypoxemic COVID patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Hospitalized patients with severe COVID-19 infection Patients requiring supplemental oxygen of 10 litres or more
Exclusion criteria:
Unco-operative patient Patients with Pneumothorax Patients with Surgical emphysema GCS less than 13 Excessive respiratory secretions Shock
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **93**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomized using a "simple" randomization method with "individuals" considered as a single unit. A table of random numbers will be generated using "https://www.randomizer.org/". One set of patients will be labeled as "controls" while the other group will be labeled as the "Interventional Group". No concealment will be carried out (open-label).
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 Pakistan Institute of Medical Sciences, Islamabad
Street address
G-8/3, Islamabad
City
Islamabad
Postal code
44080
Approval date
2021-04-21, 1400/02/01
Ethics committee reference number
ECPIMS/20/04

Health conditions studied

1

Description of health condition studied
COVID-19 Infection
ICD-10 code
J12.81
ICD-10 code description
Pneumonia due to SARS-associated coronavirus

Primary outcomes

1

Description
In-hospital mortality.
Timepoint
28 days after intervention
Method of measurement
A Questionnaire will be used to record the data.

Secondary outcomes

1

Description
The duration of hospital stay
Timepoint
28 days following the intervention
Method of measurement
A Questionnaire will be used to record the data.

2

Description
The use of non-invasive or invasive mechanical ventilation
Timepoint
28 days after intervention
Method of measurement
A Questionnaire will be used to record the data.

Intervention groups

1

Description
Intervention group: Patients in the intervention group will be applied CPAP masks for two hours in the morning and two hours in the evenings (total four hours), at least six hours apart. The CPAP pressure will be fixed at 5 mmHg. All patients in the interventional group will also receive conventional treatment. Conventional treatment will include the following: 1. Dexamethasone 6 mg intravenous once daily for 10 days, 2. Injection enoxaparin 60 mg subcutaneous once daily during the hospital stay, 3. Antibiotics as per the hospital protocol

and physician's discretion, 4. Injection omeprazole 40 mg IV once daily during the hospital stay, 5. Injection Remdesivir 200 mg IV on day one then once daily for 5 to 10 days.

Category

Treatment - Devices

2

Description

Control group: The control group will receive only the conventional treatment. Conventional treatment will include the following: 1. Dexamethasone 6 mg intravenous once daily for 10 days, 2. Injection enoxaparin 60 mg subcutaneous once daily during the hospital stay, 3. Antibiotics as per the hospital protocol and physician's discretion, 4. Injection omeprazole 40 mg IV once daily during the hospital stay, 5. Injection Remdesivir 200 mg IV on day one then once daily for 5 to 10 days.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Pakistan Institute of Medical Sciences, Islamabad.

Full name of responsible person
Ahmed Farhan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Pakistan Institute of Medical Sciences, Islamabad

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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
Pakistan Institute of Medical Sciences, Islamabad

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
Pakistan Institute of Medical Sciences, Islamabad

Full name of responsible person
Ahmed Farhan

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

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Person responsible for scientific inquiries

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Latest degree

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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
Yes - There is a plan to make this available

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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All the relevant data will be shared.

When the data will become available and for how long
Data will be available for one year following the completion of the study.

To whom data/document is available
Data will be shared with all healthcare workers and policymakers.

Under which criteria data/document could be used
Information may be requested via email to the corresponding author. Data will be shared as SPSS outcome files.

From where data/document is obtainable
Data will be provided by the corresponding author. It will be shared via email. email: drfarhan992@gmail.com

What processes are involved for a request to access data/document
Data may be provided via email on working days (Monday to Friday). It may take 3 to 5 days after the request is made.

Comments
None