

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 COVID-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

Phone

+92 51 9261592

Email address

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

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<https://emedz.net/>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Pakistan Institute of Medical Sciences, Islamabad

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

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**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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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

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