# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 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

**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**
Ahmed Farhan

**Street address**
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**City**
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**Phone**
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**Web page address**
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

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**Position**
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**Latest degree**

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**Other areas of specialty/work**
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## Person responsible for updating data

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Assistant Professor

**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