AYUB MEDICAL COLLEGE

# Effect of prone positioning on COVID-19 pneumonia/ acute respiratory distress syndrome

Study Protocols

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Title of the proposed research:

# Effect of Prone Positioning on the severity of covid pneumonia/ Acute Respiratory Distress Syndrome

**Objectives:**

To assess the efficacy and effects of prone positioning on the respiratory physiology and death rate of patients suffering from covid pneumonia/ acute respiratory distress syndrome.

**Research Questions:**

Does prone positioning increase the oxygen saturation of blood?

Does prone positioning have any effect on the severity of illness- if prone positioning has any benefits in terms of decreased severity of illness or in terms of decreased mortality at 3 months in patients with covid pneumonia?

**Data collecting tool:**

A self-developed, structured questionnaire. The questionnaire includes socio-demographic data of patients along-with parameters of pneumonia severity index.

**Data collection procedure:**

A structured questionnaire is developed and is tested before adopting the final version. Informed consent will be obtained from all the patients prior to inclusion in the study as a part of ethical practice. Data will be collected regarding personal profile/ demography of the patient by interviewing them, detailed history and thorough clinical examination and relevant investigations. Data will be collected from their medical record book/ file as well.

**Study Protocols:**

All the patients who are received in the medical emergency department as a suspected case of covid pneumonia/ acute respiratory distress syndrome (ARDS), will be assessed in the emergency department as per hospital protocols. If admitted for covid pneumonia/ ARDS, the patient will be offered to consent for participation in the study. The patients who themselves cannot consent due to severity of condition, the attendant closest in relation to the patient will be asked about the consent.

Patient will then be randomized through permuted block randomization into either a control or experimental group and shifted to the respective ward.

Complete data will be recorded on the questionnaire and will be considered as the day one of admission of the patient.

Patients in the prone position group will then be guided for prone positioning for eight hours of intermittent prone positioning. Each cycle may be from 30 minutes to 3 hours. Prone positioning was to be done under the supervision of the staff who were trained by the researchers. The prone positioning was to be done by patient him/herself after guidance with assistance if required so that patient is more comfortable.

Researcher will visit each patient twice a day to ensure if the patient was properly getting the prone positioning intervention and to assess if the patient can tolerate it. In case any complication happens due to the manoeuvre, it will be discussed with the lead investigator. The patient will be assessed for fitness to continue being part of the study or to withdraw from the study.

Record of the prone positioning cycles will be maintained by the staff in the patient file.

Seventh day will be the last day of prone positioning. Data will be recorded by the by the researcher on seventh day of admission at least ten minutes after the patient has been put to supine position.

Data will also be collected at $14^{th}$ day of admission of the patient, if the patient is still in the ward.

Patient survival at $90^{th}$ day will be confirmed by calling the patient/ attendant and requesting for death certificate in case the patient died after discharge from the facility.

**Analyses:** Data will be analysed on SPSS version 25. Statistical tests will be applied to see effect of prone positioning on the severity of covid pneumonia and acute respiratory distress syndrome and to find out its effects on mortality and respiratory physiology – $PaO_2$, respiratory rate and oxygen requirement as determined by the type of oxygen delivery mask, with a confidence interval of 95%. P value of $<0.05$ will be considered statistically significant. Data will be presented in tables, bar charts, and pie diagrams. Tests of significance will be applied to see effects of prone positioning on respiratory physiology and Kaplan Meier curve will be obtained to compare the survival of the two groups.

# Consent Form:

## TITLE OF STUDY

Proning- Effects on the severity and outcome of patients having moderate covid pneumonia.

## PURPOSE OF STUDY

You are being asked to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information. The purpose of this study is to find out the effectiveness of prone positioning (lying on belly) in this region population affected by moderate pneumonia due to covid 19 infection so that the hospital staff and doctors may be encouraged with facts and data to use such an easy maneuver to stabilize patient's oxygen saturation as we believe that prone positioning does have a protective effect against severe disease and has an effect on reducing mortality if patients are encouraged for prone positioning with proper technique and for suitable time duration as has been observed in the clinical practice in the covid wards. Therefore, we want to assess the effects of 8 hours per day prone positioning the patients with confirmed moderately severe covid pneumonia admitted in the covid wards.

## STUDY PROCEDURES

Patients admitted in the covid ward will be assessed by a doctor and categorized on the basis of the severity of their covid pneumonia as per Pneumonia Severity Index (PSI). Then the total no of patients with a PSI score of 71 to 130 will be randomized in to a control and an interventional group. Interventional group patients will be prone positioned for 8 hours per 24 hours period for a total of 7 days or until their oxygen saturation is maintained for a three day time over 90%, whichever time is longer.

Relevant data will be collected on the day of admission (DOA), on $7^{th}$ DOA, and on $14^{th}$ DOA. They will be followed up after 3 months interval through a phone call to see for survival at 3 month time.

**RISKS**

There a potential risk of cross infection of patients but it will be minimized by use of separate gloves and other gear to prevent transfer of pathogens from one patient to another. We will ensure to work on the no harm to the patient policy.

You may decline to answer any or all questions and you may terminate your involvement at any time if you choose.

**BENEFITS**

There will be no direct benefit to you for your participation in this study. However, we hope that the information obtained from this study may change the guidelines of the hospital so that the staff and doctors may be encouraged with facts and figures to use such an easy maneuver to stabilize patient's oxygen saturation as we believe that prone positioning does have a protective effect against severe disease and has an effect on reducing mortality.

**CONFIDENTIALITY**

We assure you that your name will not be divulged. Every effort will be made by the researcher to preserve your confidentiality including the following:
In written documentation, medical record numbers will be. Doctors/ Researchers will not mention the patient's name/ surnames anywhere on the questionnaire when collecting the data. Any identifying participant information will be kept in a locked file cabinet in the personal possession of the researcher.

Participant data will be kept confidential except in cases where the researcher is legally obligated to report specific incidents. These incidents include, but may not be limited to, incidents of abuse and suicide risk.

**CONTACT INFORMATION**

If you have questions at any time about this study, or you experience adverse effects as the result of participating in this study, you may contact the researcher whose contact information is provided on the first page. If you have questions regarding your rights as a research participant, or if problems arise which you do not feel you can discuss with the Primary Investigator, please contact the Institutional Review Board at (khattak@ayubmed.edu.pk)

**VOLUNTARY PARTICIPATION**

Your participation in this study is voluntary. It is up to you to decide whether or not to take part in this study. If you decide to take part in this study, you will be asked to sign a consent form. After you sign the consent form, you are still free to withdraw at any time and without giving a reason. Withdrawing from this study will not affect the relationship you have, if any, with the researcher. If you withdraw from the study before data collection is completed, your data will be returned to you or destroyed.

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**CONSENT**

I have read and I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Participant's signature _____ Date _____

Investigator's signature _____ Date _____