

## **STUDY DOCUMENT**

Official Study Title:

The Effect of Prone Position on Oxygen Saturation, Blood Gas Parameters, and Respiratory Rate in Intensive Care Patients with COVID-19-induced ARDS

NCT Number: NCTXXXXXXX

Document Type: Statistical Analysis Plan

Document Date: 26 May 2025

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# STATISTICAL ANALYSIS PLAN

## 1. Study Identification

Official Title: The Effect of Prone Position on Oxygen Saturation, Blood Gas Parameters, and Respiratory Rate in Intensive Care Patients with COVID-19-induced ARDS

NCT Number: NCTXXXXXXXX

## 2. Objectives

To determine the impact of prone positioning on:

- Oxygen saturation (SpO<sub>2</sub>, SaO<sub>2</sub>, PO<sub>2</sub>)
- Respiratory rate
- Blood gas parameters (pH, PCO<sub>2</sub>, Lactate, Sodium)

## 3. Study Design Summary

This is a randomized controlled trial with a parallel group and repeated measures over six time points.

## 4. Sample Size Justification

A total of 90 patients (45 per group) were selected using 95% confidence level, 5% margin of error, and an effect size of 0.70.

## 5. Randomization

Random assignment was done by drawing lots from every four eligible ICU admissions each day.

## 6. Outcome Measures

- Primary: Change in SpO<sub>2</sub> over six time points
- Secondary: Respiratory rate, arterial blood gas parameters (SaO<sub>2</sub>, PO<sub>2</sub>, PCO<sub>2</sub>, pH, Lactate, Sodium)

## 7. Statistical Methods

- Descriptive statistics: mean, standard deviation, frequency, and percentage
- Inferential statistics: Wilk's Lambda for repeated measures, paired t-tests, independent t-tests
- Effect size: Cohen's d
- Software: SPSS v22

## 8. Handling of Missing Data

Patients who died, were discharged, or dropped out were excluded. No imputation was used for missing values.

## 9. Analysis Population

Only patients who completed all six measurements were included in the analysis.

## **10. Version History**

Version 1.0

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