

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: NCTXXXXXXXX

Document Type: Statistical Analysis Plan

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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: NCTXXXXXXX

2. Objectives

To determine the impact of prone positioning on:

- Oxygen saturation (SpO_2 , SaO_2 , PO_2)
- Respiratory rate
- Blood gas parameters (pH, PCO_2 , 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_2 over six time points
- Secondary: Respiratory rate, arterial blood gas parameters (SaO_2 , PO_2 , PCO_2 , 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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