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

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STUDY PROTOCOL

1. Oficial Title

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

2. Brief Title

Effect of Prone Position in COVID-19 ARDS Patients

3. Principal Investigator(s)

- Dr. Veysel Tekin, RN, Ph.D. – Diyarbakır Provincial Health Directorate
- Prof. Dr. Medet Korkmaz, RN, Ph.D. – Inonu University Faculty of Nursing

4. Study Sites

General and Intermediate Intensive Care Units, Eastern Turkey

5. Study Period

Start Date: April 1, 2021
End Date: August 30, 2021

6. Background and Rationale

ARDS is a common complication of severe COVID-19, associated with high mortality. Prone positioning has been shown to improve oxygenation and lung compliance in ARDS. This study investigates its short-term effectiveness in non-intubated patients.

7. Objectives

To evaluate the impact of a 30-minute prone position on:
- Oxygen saturation (SpO_2, SaO_2, PO_2)
- Respiratory rate
- Blood gas parameters (pH, PCO_2, Lactate, Sodium)

8. Study Design

Randomized controlled trial
Parallel group, repeated measures (6 total timepoints)
1:1 allocation (n = 90, 45 per group)

9. Eligibility Criteria

Inclusion Criteria:
- Age ≥ 40
- ICU hospitalization for COVID-19-induced ARDS
- Intubated and responsive to assessment

Exclusion Criteria:
- Sensory impairments (vision/hearing)

- Cognitive impairments
- Patients who died or no longer required ICU during study

10. Intervention
Experimental Group: 30 minutes prone position once daily for 2 days
Control Group: Supine standard care

11. Outcomes
Primary Outcome:
- Change in oxygen saturation (SpO_2) post-prone positioning

Secondary Outcomes:
- Respiratory rate
- Arterial blood gas values (SaO_2, PO_2, PCO_2, pH, lactate, sodium)

12. Randomization
Simple randomization by drawing lots
Allocation ratio 1:1

13. Blinding
Open-label (no blinding)

14. Statistical Methods
Paired and independent t-tests
Wilk's Lambda
Cohen's d for effect size
SPSS used for data analysis

15. Ethical Considerations
Approval: Gazi Yasargil Training and Research Hospital Ethics Committee (15.01.2021 / No: 626)
Verbal and written consent obtained
Conducted per Declaration of Helsinki

16. Data Sharing Plan
Available upon reasonable request from the corresponding author.