Study Protocol Document

Study Title: Diagnostic and Prognostic Value of Reticulated Platelet Fraction in Patients With Ventilator-Associated Pneumonia: A Prospective Observational Study

Protocol ID: KSH-RP-VAP-2025-01

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1. Background and Rationale

Ventilator-associated pneumonia (VAP) is a common nosocomial infection in ICU patients undergoing mechanical ventilation for more than 48 hours. Traditional inflammatory markers like CRP and procalcitonin are commonly used but have limitations in early diagnosis. Reticulated Platelet Fraction (RP%) is an emerging biomarker with potential utility in early infection diagnosis and prognosis. This study aims to evaluate the diagnostic and prognostic value of RP% in VAP.

2. Objectives

Primary Objective:

- - To assess the diagnostic accuracy of RP% in patients with VAP.

Secondary Objectives:

- - To evaluate the association between RP% and 28-day mortality.
- - To explore correlations with SOFA scores and antibiotic de-escalation.

3. Study Design

This is a single-center, prospective observational cohort study to be conducted in a tertiary-level ICU. Data will be collected prospectively from patients diagnosed with VAP.

4. Population

Inclusion Criteria:

- - Age ≥18 years
- - Mechanically ventilated >48 hours
- - Diagnosed with VAP

Exclusion Criteria:

- - Pneumonia at ICU admission or as primary reason for intubation
- - MV duration <48 hours
- - Pregnancy or lactation

- - Hematologic, oncologic, or autoimmune conditions within the past 4 weeks
- - Immunosuppressive therapy or chemotherapy

5. Data Collection and Laboratory Procedures

RP% will be measured via Sysmex XN-1000 using EDTA blood samples, processed within 4 hours. Routine lab values (CRP, PCT, WBCs, etc.) and clinical data (demographics, MV duration, SOFA scores) will be collected from electronic records. Serum for CRP and PCT will be processed via Roche Cobas 8000 after centrifugation.

6. Sample Size

Based on a predicted correlation coefficient (r=0.5) between RP% and PCT, a power analysis (α=0.05, power=0.95) using G*Power resulted in a required sample size of 38. Considering a dropout margin, a total of 42 patients will be enrolled.

7. Statistical Analysis

Data will be analyzed using SPSS v26. Normality will be assessed via Kolmogorov-Smirnov test. Comparisons will be made using independent samples t-test or Mann-Whitney U test for continuous variables, and Pearson chi-square for categorical data. Correlations will be examined using Pearson or Spearman correlation based on data distribution. A p-value <0.05 will be considered significant.

8. Ethical Considerations

Ethical approval was obtained from the institutional ethics committee of Konya City Hospital. Informed consent will be obtained from all patients' legal representatives.

9. Study Timeline

Start of enrollment: July 2025

Estimated primary completion: January 2026

Study end date: February 2026

10. Principal Investigator

Name: Dr. Hasan Şenay

Institution: Konya City Hospital

Email: drhasansenay@gmail.com

Phone: +905055078822