Official Title: Investigating the Immunomodulatory Effects of Esmolol in Sepsis Management and Its Impact on Patient Outcomes

NCT Number: Pending

Study Duration: January 2020 to December 2021.

Funding Source:

Sichuan Provincial Healthcare Commission - Popularization Application Project (21PJ081); and the Sichuan Cadre Healthcare Scientific Research Project (General Subject Program) (Sichuan Cadre Research 2021-207).

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Study Protocol

Title: Esmolol in Sepsis Management: Evaluating Immunomodulatory Effects and Impact on Patient Outcomes

Objective: Evaluate the effectiveness of esmolol, a selective β1-adrenergic receptor blocker, in modulating immune responses and improving patient outcomes in sepsis.

Background: Sepsis remains a significant challenge in intensive care with high mortality rates and complex pathophysiology involving the immune system and sympathetic nervous system (SNS) interactions. This study investigates the efficacy of esmolol in modulating immune responses and improving patient outcomes in sepsis.

Methodology:

- **Study Design:** Single-center prospective controlled study comparing patient groups treated with either standard care or standard care plus esmolol based on clinical suitability and heart rate levels.
- **Participants:** 105 patients diagnosed with sepsis or septic shock, admitted to the MICU/RICU of Sichuan Provincial People's Hospital from January 2021 to December 2022, with informed consent obtained.
- **Procedures:**
    - Random assignment of patients to treatment groups.
    - Continuous monitoring and adjustment of esmolol dosage to maintain target heart rate.
    - Collection of data on inflammatory markers, immune function, hemodynamics, and clinical outcomes.
- **Ethics Approval:** Granted by the Ethics Committee of Sichuan Provincial People's Hospital.

Statistical Analysis Plan

- **Data Analysis Strategy:**
    1. Descriptive Statistics: Summarize participant characteristics using means ± standard deviations for continuous variables and frequencies for categorical variables.
    2. Effectiveness Evaluation: Perform logistic regression to evaluate the impact of esmolol on survival rates and clinical outcomes. Kaplan-Meier survival analysis with Log-rank test for comparing survival rates between treatment groups.
    3. Comparison Between Groups: Use independent samples t-tests or Mann-Whitney U tests for continuous variables and chi-square tests for categorical variables to compare the esmolol and control groups across different measures.
    4. Correlation Analysis: Assess the relationship between baseline immune function markers and treatment response using Pearson’s or Spearman’s correlation coefficients, depending on data distribution.

Software: Statistical analysis will be conducted using SPSS version 25.0 or a similar statistical package.

Ethical Considerations: Data will be anonymized to protect patient confidentiality, with all procedures carried out in accordance with the Declaration of Helsinki.