**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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**Document Date:** March 2，2024

# Informed Consent Form

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

**Principal Investigator:**
Dr. Lin Chen
Department of Pulmonary and Critical Care Medicine
Email: chenlinhx@med.uestc.edu.cn
Tel: (86)-18111585286

**Introduction:**
You are being invited to participate in a research study aimed at evaluating the effectiveness of esmolol, a selective β1-adrenergic receptor blocker, in modulating immune responses and improving outcomes for patients with sepsis. Before you decide to participate, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, family, and your healthcare providers if you wish.

**Purpose of the Study:**
This study aims to determine whether esmolol can help in managing sepsis by modulating the immune response and improving clinical outcomes compared to standard care.

**What Will Happen During the Study:**
If you agree to participate in this study:

- You will be randomly assigned to receive either standard sepsis care or standard care plus esmolol.
- Your health will be monitored closely throughout your stay in the ICU, including daily ECG monitoring to detect any changes in the QT interval.
- We will adjust the dose of esmolol as necessary based on ECG findings.
- Following discharge, you will be offered free outpatient follow-up visits for three months to monitor your recovery and any late-emerging effects of the treatment.

**Possible Risks and Discomforts:**

- Esmolol-related side effects: As with any medication, there are potential side effects including but not limited to low heart rate (bradycardia), low blood pressure (hypotension), dizziness, fatigue, heart failure, and in rare cases, arrhythmias such as AV block and QT prolongation leading to torsades de pointes.
- Procedure-related risks: Regular blood draws may cause some discomfort, bruising, infection, or other complications at the site of the needle insertion.
- Specific cardiac risks: There is a risk of developing conditions like sick sinus syndrome or tachy-brady syndrome due to AV block or prolonged QT interval. Before starting the study, we will screen for pre-existing conditions that might increase these risks, and we will monitor your

ECG closely during the study. If serious cardiac side effects develop, you may be withdrawn from the study for safety reasons.

**Potential Benefits:** While the study aims to improve the management of sepsis, there is no guarantee that you will directly benefit from participating. However, the information gathered from this study may help improve sepsis treatment for future patients.

**Emergency Situations and Handling Measures:**

- Immediate medical response: In the event of any adverse effects related to esmolol, immediate medical intervention will be available. Adjustments to the dosage or discontinuation of the drug may be necessary depending on the severity of the reaction.
- Continuous monitoring: Your health will be monitored continuously by healthcare professionals trained to respond to any complications arising from the treatment.

**Confidentiality:** Your medical records will be kept confidential as required by law. All personal information collected during the study will be stored securely and only accessible to the research team. Identifiable information will not be disclosed without your consent unless required by law.

**Participation and Withdrawal:** Your participation in this study is voluntary. You can choose to withdraw at any time without affecting your future medical care.

**Questions:** You may ask any questions you have now or at any time during the study, and before deciding whether or not to participate.

**Consent:** I have read this consent form (or it has been read to me). I have been able to ask questions about the study and any questions I had have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

**If you agree to participate, please sign below:**

**Consent:**

I have read this consent form (or it has been read to me). I have been able to ask questions about the study and any questions I had have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

If you agree to participate, please sign below:

Patient or Authorized Family Member's Signature: _____ Date: _____

Conversing Doctor's Signature: _____ Date: _____