Informed Consent Form

Official Title of Study:

The value of critical care ultrasound and noninvasive cardiac output monitoring in guiding fluid resuscitation for septic shock in the emergency department

NCT Number: PYRC-2023-088

Research institution: Emergency Department of Panyu Central Hospital

Date of Document: 2023-05-22

1. Introduction

You are invited to participate in a clinical research study conducted at the Emergency Department of Guangzhou Panyu Central Hospital. This form provides information to help you decide whether to participate. Please read carefully and ask any questions before signing. Participation is entirely voluntary. The study has been reviewed and approved by the hospital's Ethics Review Committee.

2. Purpose of the Study

The purpose of this study is to evaluate the value of critical care ultrasound and non-invasive cardiac output monitoring (NICOM) in guiding fluid resuscitation for patients with septic shock. The goal is to optimize hemodynamic management, improve prognosis, and provide evidence for selecting appropriate monitoring methods.

3. Study Design and Procedures

This is a prospective randomized controlled trial involving 60 patients diagnosed with septic shock. Participants will be randomly assigned to one of two groups:

1. Critical Care Ultrasound Group – resuscitation guided by bedside ultrasound (e.g., inferior vena cava variability, cardiac function, pulmonary B-lines).
2. Non-invasive Cardiac Output Monitoring (NICOM) Group – resuscitation guided by thoracic bioreactance-based cardiac output monitoring.

Both groups will receive standard treatment according to the 2021 Surviving Sepsis Campaign Guidelines. Data will be collected on vital signs, fluid intake within the first 6 hours, resuscitation targets, lactate clearance, complication rates, length of hospital stay, and 28-day survival.

4. Potential Risks and Discomforts

All procedures are consistent with routine clinical care. Risks include possible discomfort from ultrasound or electrode placement, and standard risks associated with septic shock treatment (e.g., arrhythmia, pulmonary edema, renal injury). If unexpected adverse events occur, the trial may be stopped for safety.

5. Potential Benefits

Participants may benefit from closer monitoring and optimized fluid management. The study may improve future clinical practice and benefit other patients with septic shock. However, there is no guarantee of direct personal benefit.

6. Alternatives

You may choose standard septic shock treatment without enrollment in this study.

7. Privacy and Confidentiality

Your medical records and study data will be kept strictly confidential. Personal identifiers will not appear in publications or reports. Authorized government agencies or ethics committee members may review data for regulatory compliance.

8. Compensation and Costs

The study-related monitoring procedures (ultrasound, NICOM) will be provided at no cost. If injury occurs as a direct result of participation, necessary medical costs will be covered by the research team according to law.

9. Voluntary Participation and Withdrawal

Participation is voluntary. You may withdraw at any time without affecting your standard medical care. If you withdraw, data collected up to that point will not be used in the analysis.

10. Contact Information

Principal Investigator: Dr. Xiaowei Mai

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11. Consent Statement

I have read and understood the study details. I have had the opportunity to ask questions, and all of my questions have been answered. I voluntarily agree to participate in this study.

Participant (or Legal Representative) Signature: _____ Date: _____

Investigator Signature: _____ Date: _____