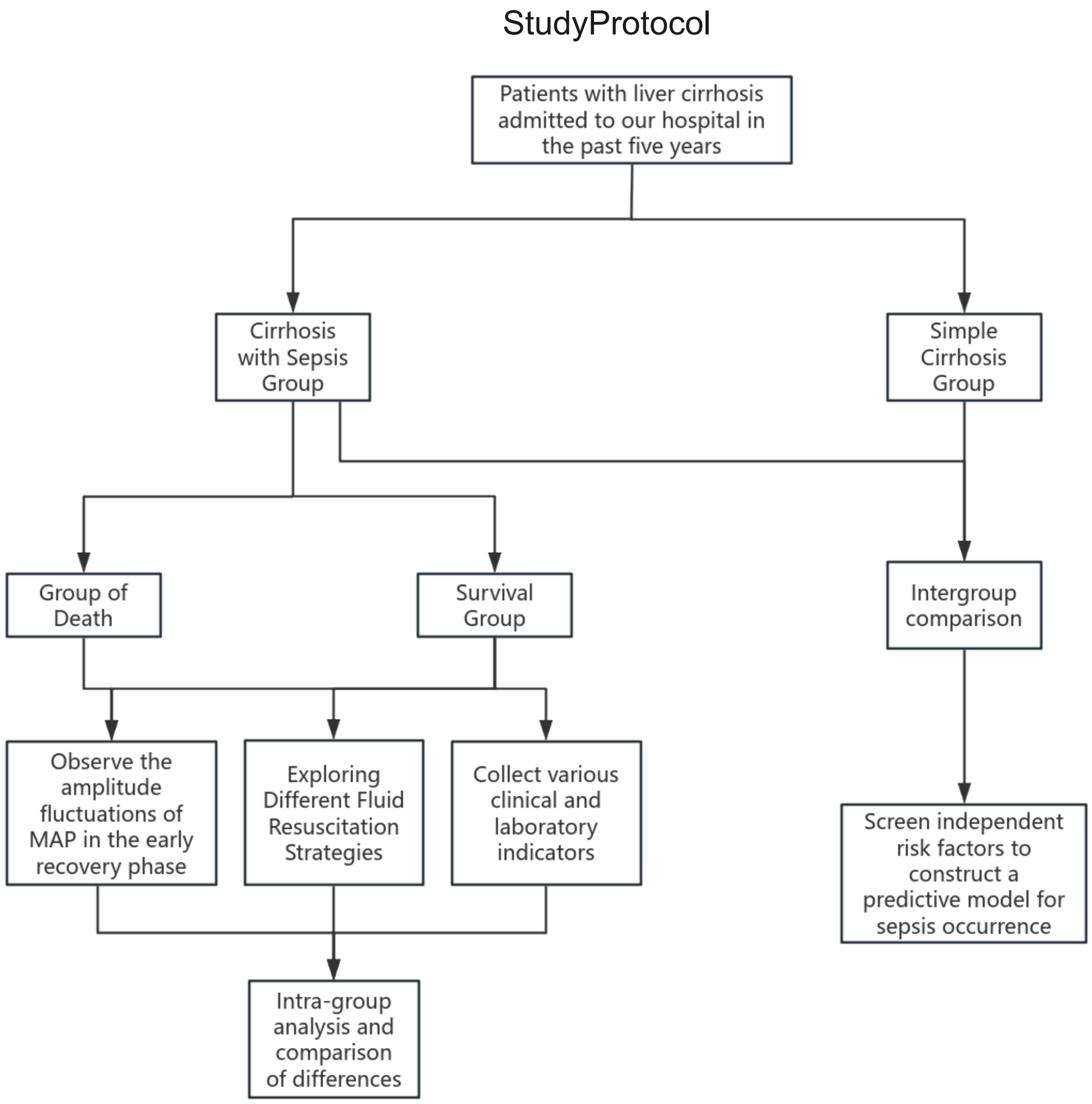
StudyProtocol
Patients with liver cirrhosis admitted to our hospital in the past five years
Cirrhosis with Sepsis Group
Simple Cirrhosis Group
Group of Death
Survival Group
Intergroup comparison
Observe the amplitude fluctuations of MAP in the early recovery phase
Exploring Different Fluid Resuscitation Strategies
Collect various clinical and laboratory indicators
Screen independent risk factors to construct a predictive model for sepsis occurrence
Intra-group analysis and comparison of differences

The Second Affiliated Hospital of Chongqing Health Medical University

THE SECOND AFFILIATED HOSPITAL OF CHONGQING MEDICAL UNIVERSITY

Review Opinion on the Scientific Research Collaboration Project of the Ethics Committee of the Second Affiliated Hospital Chongqing Medical University

Project name	Study on the Use of Antibiotics in Severe Infection and Epidemiology of Severe Infection Population		
Initiating organization	The Second Affiliated Hospital of Chongqing Medical University		
CRO company	NA		
Responsible Department	Department of Infectious Diseases	Principal Investigator	Li Shiying
Review date	19 September 2025	Review location	NA
Review method	☑summary examination Meeting review, Ethics Committee members, attendees, including, participated in voting,, abstained		
Declaration: The composition and working procedures of this ethics committee comply with ICH-GCP/China GCP and China relevant laws and regulations, and its review and working process are not influenced by any organization or individual outside the ethics committee.			
Audit-review file	1.Clinical Research Protocol (Version Number: Version 2, Version Date: May 28,2025) 2. Informed Consent Form (Version No.: Version 1, Version Date: March 28,2025) 3. Previous research data 4. Vibrio vulnificus Sulfate for Injection Instructions 5. Professional Experience of the Principal Investigator 6. Project Team Members 7. budget table 8. funding source note 9. scientific review comments 10. Commitment Letter on the Management of Human Genetic Resources for Clinical Research 11. material authenticity declaration 12. statement of conflict of interest 13. Research Results Release Format Description		

Review comments:

1. Consent to conduct the study within the hospital: Yes (details as follows)
2. In accordance with the ethical principles outlined in the "Ethical Review Measures for Life Science and Medical Research Involving Human Subjects (2023)" issued by the National Health Commission, the "Good Clinical Practice (GCP) for Drugs (2020)" by the National Medical Products Administration (NMPA), the "Good Clinical Practice (GCP) for Medical Devices (2022)" by the NMPA, the "Declaration of Helsinki" by the World Medical Association (WMA), and the "International Ethical Guidelines for Human Biomedical Research" by the International Council for Medical Sciences (CIOMS), this Ethics Committee has reviewed and approved the content of the research protocol, informed consent forms, recruitment materials, and other relevant documents for the conduct of the study.

◇ Clinical studies shall be conducted in compliance with Good Clinical Practice (GCP) principles and the protocol approved by the ethics committee, with the aim of safeguarding the health and rights of study participants.

◇ Prior to the initiation of the study, please complete the clinical trial registration or file the medical research registration with the information system for medical research registration and filing.

◇ If any modifications to the clinical research protocol, informed consent form, or recruitment materials are required due to changes in the principal investigator during the study, the applicant must submit a revised application for review.

◇ In the event of a serious adverse event, the applicant is required to submit a Serious Adverse Event Report (SAER) promptly.

◇ Please submit the research progress report 1 month prior to the deadline according to the annual/regular follow-up review frequency specified by the ethics committee. The sponsor shall submit a consolidated report on the research progress of each center to the ethics committee of the lead institution. When any situation that may significantly affect the trial progress or increase risks to study participants occurs, the applicant shall promptly submit a written report to the ethics committee.

◇ The study included participants who did not meet the inclusion criteria or met the exclusion criteria, those who were eligible to discontinue the trial but were not allowed to withdraw, those who received incorrect treatment or dosage, those who were given concomitant medications prohibited by the protocol, or those who did not adhere to the protocol. Additionally, cases that may adversely affect the rights of participants, the legal compliance of the study, or the scientific integrity of the research, thereby violating Good Clinical Practice (GCP) principles, were also included. The sponsor/inspector/researcher was requested to submit a protocol violation report.

◇ If the applicant intends to suspend or prematurely terminate the clinical study, please submit the suspension/termination research report in a timely manner.

Upon completion of the clinical study, the applicant shall submit a study completion report.

3. The study will undergo annual/periodic follow-up review by the ethics committee during its implementation, with a review frequency of once every 12 months. The ethics committee reserves the right to adjust the review frequency based on actual progress.
4. This study shall be implemented within... years from the date of approval. Any implementation carried out by Yingcai will render this opinion void and void of effect.

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Institutional Ethics Committee (seal):

2025. 9. 19

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